must provide HHS with information regarding any operational, policy, business rules, information technology, or other changes that may impact the ability of the State-based Exchange to satisfy the requirements of the pre-testing and assessment.

(d) *Submission of required data and data documentation.* As specified in §155.1510, HHS will inform State-based Exchanges about the form and manner for State-based Exchanges to submit required data and data documentation to HHS in accordance with the pre-testing and assessment plan.

(e) *Data processing.* (1) HHS will coordinate with each State-based Exchange to track and manage the data and data documentation submitted by a State-based Exchange as specified in §155.1510(a)(1) and (2).

(2) HHS will coordinate with each State-based Exchange to provide assistance in aligning the data specified in §155.1510(a)(2) from the State-based Exchange's existing data structure to the standardized set of data elements.

(3) HHS will coordinate with each State-based Exchange to interpret and validate the data specified in §155.1510(a)(2).

(4) HHS will use the data and data documentation submitted by the State-based Exchange to execute the pre-testing and assessment procedures.

(f) *Pre-testing and assessment checklist.* HHS will issue the pre-testing and assessment checklist as part of the pre-testing and assessment plan. The pre-testing and assessment checklist criteria will include but are not limited to:

(1) A State-based Exchange's submission of the data documentation as specified in §155.1510(a)(1).

(2) A State-based Exchange's submission of the data for processing and testing as specified in §155.1510(a)(2); and

(3) A State-based Exchange's completion of the pre-testing and assessment processes and procedures related to the IPPTA program.

(g) *Pre-testing and assessment report.* Subsequent to the completion of a State-based Exchange's pre-testing and assessment period, HHS will issue a pre-testing and assessment report specific to that State-based Exchange. The pre-testing and assessment report will be for HHS and State-based Exchange internal use only and will not be made available to the public by HHS unless otherwise required by law.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

Subpart A—General Provisions

Sec.

Subpart B—Essential Health Benefits Package

Subpart C—Qualified Health Plan Minimum Certification Standards

AUTHORITY: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

SOURCE: 76 FR 77411, Dec. 13, 2011, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 77 FR 18468, Mar. 27, 2012, unless otherwise noted.

§ 156.10 Basis and scope.

(a) *Basis.* (1) This part is based on the following sections of title I of the Affordable Care Act:

(i) 1301. QHP defined.

(ii) 1302. Essential health benefits requirements.

(iii) 1303. Special rules.

(iv) 1304. Related definitions.

(v) 1311. Affordable choices of health benefit plans.

(vi) 1312. Consumer choice.

(vii) 1313. Financial integrity.

(viii) 1321. State flexibility in operation and enforcement of Exchanges and related requirements.

(ix) 1322. Federal program to assist establishment and operation of nonprofit, member-run health insurance issuers.

(x) 1331. State flexibility to establish Basic Health Programs for low-income individuals not eligible for Medicaid.

(xi) 1334. Multi-State plans.

(xii) 1402. Reduced cost-sharing for individuals enrolling in QHPs.

(xiii) 1411. Procedures for determining eligibility for Exchange participation, advance premium tax credits and reduced cost sharing, and individual responsibility exemptions.

(xiv) 1412. Advance determination and payment of premium tax credits and cost-sharing reductions.

(xv) 1413. Streamlining of procedures for enrollment through an Exchange and State, Medicaid, CHIP, and health subsidy programs.

(2) This part is based on section 1150A, Pharmacy Benefit Managers Transparency Requirements, of title I of the Act:

(b) *Scope.* This part establishes standards for QHPs under Exchanges, and addresses other health insurance issuer requirements.

§ 156.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial value (AV) means the percentage paid by a health plan of the

percentage of the total allowed costs of benefits.

Applicant has the meaning given to the term in §155.20 of this subchapter.

Base-benchmark plan means the plan that is selected by a State from the options described in §156.100(a) of this subchapter, or a default benchmark plan, as described in §156.100(c) of this subchapter, prior to any adjustments made pursuant to the benchmark standards described in §156.110 of this subchapter.

Benefit design standards means coverage that provides for all of the following:

(1) The essential health benefits as described in section 1302(b) of the Affordable Care Act;

(2) Cost-sharing limits as described in section 1302(c) of the Affordable Care Act; and

(3) A bronze, silver, gold, or platinum level of coverage as described in section 1302(d) of the Affordable Care Act, or is a catastrophic plan as described in section 1302(e) of the Affordable Care Act.

Benefit year has the meaning given to the term in §155.20 of this subtitle.

Cost-sharing has the meaning given to the term in §155.20 of this subtitle.

Cost-sharing reductions has the meaning given to the term in §155.20 of this subtitle.

Delegated entity means any party, including an agent or broker, that enters into an agreement with a QHP issuer to provide administrative services or health care services to qualified individuals, qualified employers, or qualified employees and their dependents.

Downstream entity means any party, including an agent or broker, that enters into an agreement with a delegated entity or with another downstream entity for purposes of providing administrative or health care services related to the agreement between the delegated entity and the QHP issuer. The term ''downstream entity'' is intended to reach the entity that directly provides administrative services or health care services to qualified individuals, qualified employers, or qualified employees and their dependents.

EHB-benchmark plan means the standardized set of essential health benefits that must be met by a QHP, as defined in §155.20 of this section, or other issuer as required by §147.150 of this subchapter.

Enrollee satisfaction survey vendor means an organization that has relevant survey administration experience (for example, CAHPS® surveys), organizational survey capacity, and quality control procedures for survey administration.

Essential health benefits package or EHB package means the scope of covered benefits and associated limits of a health plan offered by an issuer that provides at least the ten statutory categories of benefits, as described in §156.110(a) of this subchapter; provides the benefits in the manner described in §156.115 of this subchapter; limits cost sharing for such coverage as described in §156.130; and subject to offering catastrophic plans as described in section 1302(e) of the Affordable Care Act, provides distinct levels of coverage as described in §156.140 of this subchapter.

Federally-facilitated SHOP has the meaning given to the term in §155.20 of this subchapter.

Group health plan has the meaning given to the term in §144.103 of this subtitle.

Health insurance coverage has the meaning given to the term in §144.103 of this subtitle.

Health insurance issuer or issuer has the meaning given to the term in §144.103 of this subtitle.

Issuer group means all entities treated under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 as a member of the same controlled group of corporations as (or under common control with) a health insurance issuer, or issuers affiliated by the common use of a nationally licensed service mark.

Level of coverage means one of four standardized actuarial values as defined by section 1302(d)(1) of the Affordable Care Act of plan coverage.

Percentage of the total allowed costs of benefits means the anticipated covered medical spending for EHB coverage (as defined in §156.110(a) of this subchapter) paid by a health plan for a standard population, computed in accordance with the plan's cost-sharing,

divided by the total anticipated allowed charges for EHB coverage provided to a standard population, and expressed as a percentage.

Plan has the meaning given the term in § 144.103 of this subchapter.

Plan year has the meaning given to the term in § 155.20 of this subchapter.

Qualified employer has the meaning given to the term in § 155.20 of this subchapter.

Qualified health plan has the meaning given to the term in § 155.20 of this subchapter.

Qualified health plan issuer has the meaning given to the term in § 155.20 of this subchapter.

Qualified individual has the meaning given to the term in § 155.20 of this subchapter.

Registered user of the enrollee satisfaction survey data warehouse means enrollee satisfaction survey vendors, QHP issuers, and Exchanges authorized to access CMS's secure data warehouse to submit survey data and to preview survey results prior to public reporting.

[77 FR 18468, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012; 78 FR 12865, Feb. 25, 2013; 78 FR 15535, Mar. 11, 2013; 78 FR 54142, Aug. 30, 2013; 78 FR 65096, Oct. 30, 2013; 80 FR 10871, Feb. 27, 2015; 84 FR 17567, Apr. 25, 2019; 85 FR 29261, May 14, 2020]

§ 156.50 Financial support.

(a) *Definitions.* The following definitions apply for the purposes of this section:

Participating issuer means any issuer offering a plan that participates in the specific function that is funded by user fees. This term may include: health insurance issuers, QHP issuers, issuers of multi-State plans (as defined in § 155.1000(a) of this subchapter), issuers of stand-alone dental plans (as described in § 155.1065 of this subtitle), or other issuers identified by an Exchange.

(b) *Requirement for State-based Exchange user fees.* A participating issuer must remit user fee payments, or any other payments, charges, or fees, if assessed by a State-based Exchange under § 155.160 of this subchapter.

(c) *Requirement for Exchange user fees.* (1) To support the functions of Federally-facilitated Exchanges, a participating issuer offering a plan through a Federally-facilitated Exchange must remit a user fee to HHS each month, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for Federally-facilitated Exchanges for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through a Federally-facilitated Exchange.

(2) To support the functions of State Exchanges on the Federal platform, unless the State Exchange and HHS agree on an alternative mechanism to collect the funds, a participating issuer offering a plan through a State Exchange on the Federal Exchange platform for certain Exchange functions described in § 155.200 of this subchapter, as specified in a Federal platform agreement, must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the sum of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for State Exchanges on the Federal platform for the applicable benefit year, multiplied by the monthly premium charged by the issuer for each policy under the plan where enrollment is through the State-based Exchange on the Federal platform.

(d) *Adjustment of Exchange user fees.* (1) A participating issuer offering a plan through a Federally-facilitated Exchange or State Exchange on the Federal platform may qualify for an adjustment of the Federally-facilitated Exchange user fee specified in paragraph (c)(1) of this section or the State Exchange on the Federal platform user fee specified in paragraph (c)(2) of this section, to the extent that the participating issuer—

(i) Made payments for contraceptive services on behalf of a third party administrator pursuant to 26 CFR 54.9815–2713A(b)(2)(ii) or 29 CFR 2590.715–2713A(b)(2)(ii); or

(ii) Seeks an adjustment in the Federally-facilitated Exchange user fee with respect to a third party administrator that, following receipt of a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR

2590.715–2713A(a)(4), made or arranged for payments for contraceptive services pursuant to 26 CFR 54.9815–2713A(b)(2)(i) or (ii) or 29 CFR 2590.715–2713A(b)(2)(i) or (ii).

(2) For a participating issuer described in paragraph (d)(1) of this section to receive an adjustment of a user fee under this section—

(i) The participating issuer must submit to HHS, in the manner and timeframe specified by HHS, in the year following the calendar year in which the contraceptive services for which payments were made pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) were provided —

(A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) or with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, whether or not the participating issuer was the entity that made the payments for contraceptive services;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by a third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable; and

(C) For each such self-insured group health plan, the total dollar amount of the payments that were made pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) for contraceptive services that were provided during the applicable calendar year. If such payments were made by the participating issuer directly as described in paragraph (d)(1)(i) of this section, the total dollar amount should reflect the amount of the payments made by the participating issuer; if the third party administrator made or arranged for such payments, as described in paragraph (d)(1)(ii) of this section, the total dollar amount should reflect the amount reported to the participating issuer by the third party administrator.

(ii) Each third party administrator that intends to seek an adjustment on behalf of a participating issuer of the Federally-facilitated Exchange user fee or the State-based Exchange on the Federal platform user fee based on payments for contraceptive services, must submit to HHS a notification of such intent, in a manner specified by HHS, by the 60th calendar day following the date on which the third party administrator receives the applicable copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4).

(iii) Each third party administrator identified in paragraph (d)(2)(i)(A) of this section must submit to HHS, in the manner and timeframe specified by HHS, in the year following the calendar year in which the contraceptive services for which payments were made pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) were provided—

(A) Identifying information for the third party administrator and the participating issuer;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by the third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable;

(C) The total number of participants and beneficiaries in each such self-insured group health plan during the applicable calendar year;

(D) For each such self-insured group health plan with respect to which the third party administrator made payments pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) for contraceptive services, the total dollar amount of such payments that were provided during the applicable calendar year. If such payments were made by the participating issuer directly as described in paragraph (d)(1)(i) of this section, the total dollar amount should reflect the

amount reported to the third party administrator by the participating issuer; if the third party administrator made or arranged for such payments, as described in paragraph (d)(1)(ii) of this section, the total dollar amount should reflect the amount of the payments made by or on behalf of the third party administrator; and

(E) An attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2).

(3) If the requirements set forth in paragraph (d)(2) of this section are met, the participating issuer will be provided a reduction in its obligation to pay the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, equal in value to the sum of the following:

(i) The total dollar amount of the payments for contraceptive services submitted by the applicable third-party administrators, as described in paragraph (d)(2)(iii)(D) of this section; and

(ii) An allowance for administrative costs and margin. The allowance will be no less than 10 percent of the total dollar amount of the payments for contraceptive services specified in paragraph (d)(3)(i) of this section. HHS will specify the allowance for a particular calendar year in the annual HHS notice of benefit and payment parameters.

(4) If the amount of the adjustment under paragraph (d)(3) of this section is greater than the amount of the participating issuer's obligation to pay the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, in a particular month, the participating issuer will be provided a credit in succeeding months in the amount of the excess.

(5) Within 60 days of receipt of any adjustment of a user fee under this section, a participating issuer must pay each third party administrator with respect to which it received any portion of such adjustment an amount that is no less than the portion of the adjustment attributable to the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D) of this section. No such payment is required with respect to the allowance for administrative costs and margin described in paragraph (d)(3)(ii) of this section. This paragraph does not apply if the participating issuer made the payments for contraceptive services on behalf of the third party administrator, as described in paragraph (d)(1)(i) of this section, or is in the same issuer group as the third party administrator.

(6) A participating issuer that receives an adjustment in the user fee specified in paragraph (c)(1) or (2) of this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it timely paid each third party administrator with respect to which it received any such adjustment any amount required to be paid to the third party administrator under paragraph (d)(5) of this section.

(7) A third party administrator of a plan with respect to which an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section is received under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, all of the following documentation:

(i) A copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) for each self-insured plan with respect to which an adjustment is received.

(ii) Documentation demonstrating that the payments for contraceptive services were made in compliance with 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2).

(iii) Documentation supporting the total dollar amount of the payments for contraceptive services submitted by

the third party administrator, as described in paragraph (d)(2)(iii)(D) of this section.

[77 FR 18468, Mar. 27, 2012, as amended at 78 FR 15535, Mar. 11, 2013; 78 FR 39897, July 2, 2013; 81 FR 12348, Mar. 8, 2016; 83 FR 62498, Dec. 4, 2018; 86 FR 24290, May 5, 2021; 87 FR 27389, May 6, 2022]

§ 156.80 Single risk pool.

(a) *Individual market.* A health insurance issuer must consider the claims experience of all enrollees in all health plans (other than grandfathered health plans) subject to section 2701 of the Public Health Service Act and offered by such issuer in the individual market in a state, including those enrollees who do not enroll in such plans through the Exchange, to be members of a single risk pool.

(b) *Small group market.* A health insurance issuer must consider the claims experience of all enrollees in all health plans (other than grandfathered health plans) subject to section 2701 of the Public Health Service Act and offered by such issuer in the small group market in a state, including those enrollees who do not enroll in such plans through the Exchange, to be members of a single risk pool.

(c) *Merger of the individual and small group markets.* A state may require the individual and small group insurance markets within a state to be merged into a single risk pool if the state determines appropriate. A state that requires such merger must submit to CMS information on its election in accordance with the procedures described in §147.103 of this subchapter.

(d) *Index rate*—(1) *In general.* A health insurance issuer must establish an index rate that is effective January 1 of each calendar year for a State market described in paragraphs (a) through (c) of this section.

(i) The index rate must be based on the total combined claims costs for providing essential health benefits within the single risk pool of that State market.

(ii) The index rate must be adjusted on a market-wide basis for the State based on the total expected market-wide payments and charges under the risk adjustment program and Exchange user fees (expected to be remitted under §156.50(b) or (c) and (d) as applicable, plus the dollar amount under §156.50(d)(3)(i) and (ii) expected to be credited against user fees payable for that State market).

(iii) The premium rate for all of the health insurance issuer's plans in the relevant State market must use the applicable market-wide adjusted index rate, subject only to the plan-level adjustments permitted in paragraph (d)(2) of this section.

(2) *Permitted plan-level adjustments to the index rate.* For plan years or policy years beginning on or after January 1, 2014, a health insurance issuer may vary premium rates for a particular plan from its market-wide index rate for a relevant state market based only on the following actuarially justified plan-specific factors:

(i) The actuarial value and cost-sharing design of the plan.

(ii) The plan's provider network, delivery system characteristics, and utilization management practices.

(iii) The benefits provided under the plan that are in addition to the essential health benefits. These additional benefits must be pooled with similar benefits within the single risk pool and the claims experience from those benefits must be utilized to determine rate variations for plans that offer those benefits in addition to essential health benefits.

(iv) Administrative costs, excluding Exchange user fees.

(v) With respect to catastrophic plans, the expected impact of the specific eligibility categories for those plans.

(3) *Calibration.* The issuer must calibrate the plan-adjusted index rate for its plans within the single risk pool to correspond to an age rating factor of 1.0, a geographic rating factor of 1.0, and a tobacco use rating factor of 1.0, in a manner specified by the Secretary in guidance, to ensure that any rating variation under §147.102 of this subchapter may be accurately applied with respect to a particular plan or coverage. The calibration must be applied uniformly to all plans within the single risk pool of the State market and cannot vary by plan.

(4) *Frequency of index rate and plan-level adjustments.* (i) A health insurance

issuer may not establish an index rate and make the market-wide adjustments pursuant to paragraph (d)(1) of this section, make the plan-level adjustments pursuant to paragraph (d)(2) of this section, or calibrate the plan-adjusted index rate for its plans pursuant to paragraph (d)(3) of this section more or less frequently than annually, except as provided in paragraph (d)(4)(ii) of this section.

(ii) A health insurance issuer in the small group market (not including a merged market) may establish index rates and make the marketwide adjustments under paragraph (d)(1) of this section, make the plan-level adjustments under paragraph (d)(2) of this section, and calibrate the plan-adjusted index rate for its plans pursuant to paragraph (d)(3) of this section, no more frequently than quarterly. Any changes to rates must have effective dates of January 1, April 1, July 1, or October 1. Such rates may only apply to coverage issued or renewed on or after the rate effective date and will apply for the entire plan year of the group health plan.

(e) *Grandfathered health plans in the individual and small group market.* A state law requiring grandfathered health plans described in §147.140 of this subchapter to be included in a single risk pool described in paragraphs (a) through (c) of this section does not apply.

(f) *Applicability date.* The provisions of this section apply for plan years (as that term is defined in §144.103 of this subchapter) in the group market, and for policy years (as that term is defined in §144.103 of this subchapter) in the individual market, beginning on or after January 1, 2014.

[78 FR 13441, Feb. 27, 2013, as amended at 78 FR 39898, July 2, 2013; 78 FR 65096, Oct. 30, 2013; 81 FR 12349, Mar. 8, 2016; 81 FR 94180, Dec. 22, 2016]

Subpart B—Essential Health Benefits Package

SOURCE: 78 FR 12866, Feb. 25, 2013, unless otherwise noted.

§ 156.100 State selection of benchmark plan for plan years beginning prior to January 1, 2020.

For plan years beginning before January 1, 2020, each State may identify a base-benchmark plan according to the selection criteria described below:

(a) *State selection of base-benchmark plan.* The options from which a base-benchmark plan may be selected by the State are the following:

(1) *Small group market health plan.* The largest health plan by enrollment in any of the three largest small group insurance products by enrollment, as defined in §159.110 of this subpart, in the State's small group market as defined in §155.20 of this subchapter.

(2) *State employee health benefit plan.* Any of the largest three employee health benefit plan options by enrollment offered and generally available to State employees in the State involved.

(3) *FEHBP plan.* Any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by aggregate enrollment that is offered to all health-benefits-eligible federal employees under 5 USC 8903.

(4) *HMO.* The coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the State.

(b) *EHB-benchmark selection standards.* In order to become an EHB-benchmark plan as defined in §156.20 of this subchapter, a state-selected base-benchmark plan must meet the requirements for coverage of benefits and limits described in §156.110 of this subpart; and

(c) *Default base-benchmark plan.* If a State does not make a selection using the process described in this section, the default base-benchmark plan will be the largest plan by enrollment in the largest product by enrollment in the State's small group market.

(d) *Applicability date:* For plan years beginning on or after January 1, 2020, §156.111 applies in place of this section.

[78 FR 12866, Feb. 25, 2013, as amended at 80 FR 10871, Feb. 27, 2015; 83 FR 17068, Apr. 17, 2018]

§ 156.105 Determination of EHB for multi-state plans.

A multi-state plan must meet benchmark standards set by the U.S. Office of Personnel Management.

§ 156.110 EHB-benchmark plan standards.

An EHB-benchmark plan must meet the following standards:

(a) *EHB coverage.* Provide coverage of at least the following categories of benefits:

(1) Ambulatory patient services.

(2) Emergency services.

(3) Hospitalization.

(4) Maternity and newborn care.

(5) Mental health and substance use disorder services, including behavioral health treatment.

(6) Prescription drugs.

(7) Rehabilitative and habilitative services and devices.

(8) Laboratory services.

(9) Preventive and wellness services and chronic disease management.

(10) Pediatric services, including oral and vision care.

(b) *Coverage in each benefit category.* A base-benchmark plan not providing any coverage in one or more of the categories described in paragraph (a) of this section, must be supplemented as follows:

(1) *General supplementation methodology.* A base-benchmark plan that does not include items or services within one or more of the categories described in paragraph (a) of this section must be supplemented by the addition of the entire category of such benefits offered under any other benchmark plan option described in §156.100(a) of this subpart unless otherwise described in this subsection.

(2) *Supplementing pediatric oral services.* A base-benchmark plan lacking the category of pediatric oral services must be supplemented by the addition of the entire category of pediatric oral benefits from one of the following:

(i) The FEDVIP dental plan with the largest national enrollment that is described in and offered to federal employees under 5 U.S.C. 8952; or

(ii) The benefits available under that State's separate CHIP plan, if a separate CHIP plan exists, to the eligibility group with the highest enrollment.

(3) *Supplementing pediatric vision services.* A base-benchmark plan lacking the category of pediatric vision services must be supplemented by the addition of the entire category of pediatric vision benefits from one of the following:

(i) The FEDVIP vision plan with the largest national enrollment that is offered to federal employees under 5 USC 8982; or

(ii) The benefits available under the State's separate CHIP plan, if a separate CHIP plan exists, to the eligibility group with the highest enrollment.

(c) *Supplementing the default base-benchmark plan.* A default base-benchmark plan as defined in §156.100(c) of this subpart that lacks any categories of essential health benefits will be supplemented by HHS in the following order, to the extent that any of the plans offer benefits in the missing EHB category:

(1) The largest plan by enrollment in the second largest product by enrollment in the State's small group market, as defined in §155.20 of this subchapter (except for pediatric oral and vision benefits);

(2) The largest plan by enrollment in the third largest product by enrollment in the State's small group market, as defined in §155.20 of this subchapter (except for pediatric oral and vision benefits);

(3) The largest national FEHBP plan by enrollment across States that is offered to federal employees under 5 USC 8903 (except for pediatric oral and vision benefits);

(4) The plan described in paragraph (b)(2)(i) of this section for pediatric oral care benefits; and

(5) The plan described in paragraph (b)(3)(i) of this section for pediatric vision care benefits.

(d) *Non-discrimination.* Not include discriminatory benefit designs that contravene the non-discrimination standards defined in §156.125 of this subpart.

(e) *Balance.* Ensure an appropriate balance among the EHB categories to ensure that benefits are not unduly weighted toward any category.

(f) *Determining habilitative services.* If the base-benchmark plan does not include coverage for habilitative services, the State may determine which services are included in that category.

[78 FR 12866, Feb. 25, 2013, as amended at 80 FR 10871, Feb. 27, 2015]

§ 156.111 State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020.

(a)(1) Subject to paragraphs (b) through (e) of this section, for plan years beginning on or after January 1, 2020, through December 31, 2025, a State may change its EHB-benchmark plan by:

(i) Selecting the EHB-benchmark plan that another State used for the 2017 plan year under §§156.100 and 156.110;

(ii) Replacing one or more categories of EHBs established at §156.110(a) in the State's EHB-benchmark plan used for the 2017 plan year with the same category or categories of EHB from the EHB-benchmark plan that another State used for the 2017 plan year under §§156.100 and 156.110; or

(iii) Otherwise selecting a set of benefits that would become the State's EHB-benchmark plan.

(2) Subject to paragraphs (b) through (e) of this section, for plan years beginning on or after January 1, 2026, a State may change its EHB-benchmark plan by selecting a set of benefits that would become the State's EHB-benchmark plan.

(b) A State's EHB-benchmark plan must:

(1) *EHB coverage.* Provide coverage of items and services for at least the categories of benefits at §156.110(a), including an appropriate balance of coverage for these categories of benefits.

(2) *Scope of benefits.* (i) For plan years beginning on or after January 1, 2020, through December 31, 2025:

(A) Provide a scope of benefits equal to the scope of benefits provided under a typical employer plan (supplemented by the State as necessary to provide coverage within each EHB category at §156.110(a)), defined as either:

(*1*) One of the selecting State's 10 base-benchmark plan options established at §156.100, and available for the selecting State's selection for the 2017 plan year; or

(*2*) The largest health insurance plan by enrollment within one of the five largest large group health insurance products by enrollment in the State, as product and plan are defined at §144.103 of this subchapter, provided that:

(*i*) The product has at least 10 percent of the total enrollment of the five largest large group health insurance products in the State;

(*ii*) The plan provides minimum value, as defined under §156.145;

(*iii*) The benefits are not excepted benefits, as established under §§146.145(b), and 148.220 of this subchapter; and

(*iv*) The benefits in the plan are from a plan year beginning after December 31, 2013.

(B) Not exceed the generosity of the most generous among a set of comparison plans, including:

(*1*) The State's EHB-benchmark plan used for the 2017 plan year, and

(*2*) Any of the State's base-benchmark plan options for the 2017 plan year described in §156.100(a)(1), supplemented as necessary under §156.110.

(ii) For plan years beginning on or after January 1, 2026, provide a scope of benefits that is equal to the scope benefits of a typical employer plan in the State. The scope of benefits in a typical employer plan in a State is any scope of benefits that is as or more generous than the scope of benefits in the least generous plan (supplemented by the State as necessary to provide coverage within each EHB category at §156.110(a)), and as or less generous than the scope of benefits in the most generous plan in the State (supplemented by the State as necessary to provide coverage within each EHB category at §156.110(a)), among the following:

(A) One of the selecting State's 10 base-benchmark plan options established at §156.100, and available for the selecting State's selection for the 2017 plan year; or

(B) The largest health insurance plan by enrollment within one of the five largest large group health insurance products by enrollment in the State, as product and plan are defined at §144.103 of this subchapter, provided that:

(*1*) The product has at least 10 percent of the total enrollment of the five largest large group health insurance products in the State;

(*2*) The plan provides minimum value, as defined under §156.145;

(*3*) The benefits are not excepted benefits, as established under §146.145(b), and §148.220 of this subchapter; and

(*4*) The benefits in the plan are from a plan year beginning after December 31, 2013.

(c) The State must provide reasonable public notice and an opportunity for public comment on the State's selection of an EHB-benchmark plan that includes posting a notice on its opportunity for public comment with associated information on a relevant State website.

(d) A State must notify HHS of the selection of a new EHB-benchmark plan by the first Wednesday in May of the year that is 2 years before the effective date of the new EHB-benchmark plan.

(1) If the State does not make a selection by the first Wednesday in May of the year that is 2 years before the effective date of the new EHB-benchmark plan, or its benchmark plan selection does not meet the requirements of this section and section 1302 of the ACA, the State's EHB-benchmark plan for the applicable plan year will be that State's EHB-benchmark plan applicable for the prior year.

(2) [Reserved]

(e) A State changing its EHB-benchmark plan under this section must submit documents in a format and manner specified by HHS by the first Wednesday in May of the year that is 2 years before the effective date of the new EHB-benchmark plan. These must include:

(1) A document confirming that the State's EHB-benchmark plan definition complies with the requirements under paragraphs (a), (b) and (c) of this section, including information on which selection option under paragraph (a) of this section the State is using, and whether the State is using another State's EHB-benchmark plan;

(2) An actuarial certification and an associated actuarial report from an actuary, who is a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies, that affirms that the State's EHB-benchmark plan complies with the applicable scope of benefits requirements at paragraph (b)(2) of this section.

(3) The State's EHB-benchmark plan document that reflects the benefits and limitations, including medical management requirements, a schedule of benefits and, if the State is changing the number of prescription drugs pursuant to §156.122(a)(1)(ii), a formulary drug list in a format and manner specified by HHS; and

(4) Other documentation specified by HHS, which is necessary to operationalize the State's EHB-benchmark plan.

[83 FR 17068, Apr. 17, 2018, as amended at 85 FR 29261, May 14, 2020; 87 FR 27390, May 6, 2022; 89 FR 26424, Apr. 15, 2024]

§156.115 Provision of EHB.

(a) Provision of EHB means that a health plan provides benefits that—

(1) Are substantially equal to the EHB-benchmark plan including:

(i) Covered benefits;

(ii) Limitations on coverage including coverage of benefit amount, duration, and scope; and

(iii) Prescription drug benefits that meet the requirements of §156.122 of this subpart;

(2) With the exception of the EHB category of coverage for pediatric services, do not exclude an enrollee from coverage in an EHB category.

(3) With respect to the mental health and substance use disorder services, including behavioral health treatment services, required under §156.110(a)(5), comply with the requirements under section 2726 of the Public Health Service Act and its implementing regulations.

(4) Include preventive health services described in §147.130 of this subchapter.

(5) With respect to habilitative services and devices—

(i) Cover health care services and devices that help a person keep, learn, or improve skills and functioning for daily living (habilitative services). Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy,

speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings;

(ii) Do not impose limits on coverage of habilitative services and devices that are less favorable than any such limits imposed on coverage of rehabilitative services and devices; and

(iii) For plan years beginning on or after January 1, 2017, do not impose combined limits on habilitative and rehabilitative services and devices.

(6) For plan years beginning on or after January 1, 2016, for pediatric services that are required under §156.110(a)(10), provide coverage for enrollees until at least the end of the month in which the enrollee turns 19 years of age.

(b) An issuer of a plan offering EHB may substitute benefits for those provided in the EHB-benchmark plan under the following conditions—

(1) The issuer substitutes a benefit that:

(i) Is actuarially equivalent to the benefit that is being replaced as determined in paragraph (b)(4) of this section; and

(ii) Is not a prescription drug benefit.

(2) An issuer may substitute a benefit within the same EHB category, unless prohibited by applicable State requirements. Substitution of benefits between EHB categories is not permitted.

(3) The plan that includes substituted benefits must:

(i) Continue to comply with the requirements of paragraph (a) of this section, including by providing benefits that are substantially equal to the EHB-benchmark plan;

(ii) Provide an appropriate balance among the EHB categories such that benefits are not unduly weighted toward any category; and

(iii) Provide benefits for diverse segments of the population.

(4) The issuer submits to the State evidence of actuarial equivalence that is:

(i) Certified by a member of the American Academy of Actuaries;

(ii) Based on an analysis performed in accordance with generally accepted actuarial principles and methodologies;

(iii) Based on a standardized plan population; and

(iv) Determined without taking cost-sharing into account.

(c) A health plan does not fail to provide EHB solely because it does not offer the services described in §156.280(d) of this subchapter.

(d) For plan years beginning on or before January 1, 2026, an issuer of a plan offering EHB may not include routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia as EHB. For plan years beginning on or after January 1, 2027, an issuer of a plan offering EHB may not include routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia as EHB.

[78 FR 12866, Feb. 25, 2013, as amended at 80 FR 10871, Feb. 27, 2015; 81 FR 12349, Mar. 8, 2016; 83 FR 17069, Apr. 17, 2018; 86 FR 53506, Sept. 27, 2021; 87 FR 27390, May 6, 2022; 89 FR 26425, Apr. 15, 2024]

§156.120 Collection of data to define essential health benefits.

(a) *Definitions.* The following definitions apply to this section, unless the context indicates otherwise:

Health benefits means benefits for medical care, as defined at §144.103 of this subchapter, which may be delivered through the purchase of insurance or otherwise.

Health plan has the meaning given to the term ''Portal Plan'' in §159.110 of this subchapter.

State has the meaning given to that term in §155.20 of this subchapter.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment. Treatment limitations include only quantitative treatment limitations. A permanent exclusion of all benefits for a particular condition or disorder is not a treatment limitation.

(b) *Reporting requirement.* A State that selects a base-benchmark plan or an issuer that offers a default base-benchmark plan in accordance with §156.100 must submit to HHS the following information in a form and manner, and by a date, determined by HHS:

(1) Administrative data necessary to identify the health plan;

(2) Data and descriptive information for each plan on the following items:

(i) All health benefits in the plan;

(ii) Treatment limitations;

(iii) Drug coverage; and

(iv) Exclusions.

[80 FR 10871, Feb. 27, 2015]

§ 156.122 Prescription drug benefits.

(a) A health plan does not provide essential health benefits unless it:

(1) Subject to the exception in paragraph (b) of this section, covers at least the greater of:

(i) One drug in every United States Pharmacopeia (USP) category and class; or

(ii) The same number of prescription drugs in each category and class as the EHB-benchmark plan;

(2) Submits its formulary drug list to the Exchange, the State or OPM; and

(3) For plans years beginning on or after January 1, 2017, uses a pharmacy and therapeutics (P&T) committee that meets the following standards.

(i) *Membership standards.* The P&T committee must:

(A) Have members that represent a sufficient number of clinical specialties to adequately meet the needs of enrollees.

(B) Consist of a majority of individuals who are practicing physicians, practicing pharmacists and other practicing health care professionals who are licensed to prescribe drugs.

(C) Prohibit any member with a conflict of interest with respect to the issuer or a pharmaceutical manufacturer from voting on any matters for which the conflict exists.

(D) Require at least 20 percent of its membership to have no conflict of interest with respect to the issuer and any pharmaceutical manufacturer.

(E) For plan years beginning on or after January 1, 2026, include at minimum one patient representative who must:

(*1*) Represent the patient perspective as a member of the P&T committee.

(*2*) Have relevant experience or participation in patient or community-based organizations.

(*3*) Be able to demonstrate the ability to integrate data interpretations with practical patient considerations.

(*4*) Have no fiduciary obligation to a health facility or other health agency and have no material financial interest in the rendering of health services.

(*5*) Have a broad understanding of one or more conditions or diseases, associated treatment options, and research.

(*6*) Disclose financial interests on their conflict-of-interest statements. Disclosed financial interests must include all interests with any entity that would benefit from decisions regarding plan formularies as well as specific information about their financial interests, such as the nature of the relationship and the value of the financial interest.

(ii) *Meeting standards.* The P&T committee must:

(A) Meet at least quarterly.

(B) Maintain written documentation of the rationale for all decisions regarding formulary drug list development or revision.

(iii) *Formulary drug list establishment and management.* The P&T committee must:

(A) Develop and document procedures to ensure appropriate drug review and inclusion.

(B) Base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(C) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs.

(D) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange.

(E) Evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually.

(F) Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug.

(G) Review new FDA-approved drugs and new uses for existing drugs.

(H) Ensure the issuer's formulary drug list:

(*1*) Covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states, and does not discourage enrollment by any group of enrollees; and

(*2*) Provides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

(b) A health plan does not fail to provide EHB prescription drug benefits solely because it does not offer drugs approved by the Food and Drug Administration as a service described in § 156.280(d) of this subchapter.

(c) A health plan providing essential health benefits must have the following processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (a request for exception). In the event that an exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under § 156.130 and when calculating the plan's actuarial value under § 156.135.

(1) *Standard exception request.* For plans years beginning on or after January 1, 2016:

(i) A health plan must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request a standard review of a decision that a drug is not covered by the plan.

(ii) A health plan must make its determination on a standard exception and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following receipt of the request.

(iii) A health plan that grants a standard exception request must provide coverage of the non-formulary drug for the duration of the prescription, including refills.

(2) *Expedited exception request.* (i) A health plan must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request an expedited review based on exigent circumstances.

(ii) Exigent circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug.

(iii) A health plan must make its coverage determination on an expedited review request based on exigent circumstances and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 24 hours following receipt of the request.

(iv) A health plan that grants an exception based on exigent circumstances must provide coverage of the non-formulary drug for the duration of the exigency.

(3) *External exception request review.* For plans years beginning on or after January 1, 2016:

(i) If the health plan denies a request for a standard exception under paragraph (c)(1) of this section or for an expedited exception under paragraph (c)(2) of this section, the health plan must have a process for the enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request that the original exception request and subsequent denial of such request be reviewed by an independent review organization.

(ii) A health plan must make its determination on the external exception request and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following its receipt of the request, if the original request was a standard exception request under paragraph (c)(1) of this section, and no later than 24 hours following its receipt of the request, if the original request was an expedited exception request under paragraph (c)(2) of this section.

(iii) If a health plan grants an external exception review of a standard exception request, the health plan must provide coverage of the non-formulary drug for the duration of the prescription. If a health plan grants an external exception review of an expedited exception request, the health plan must provide coverage of the non-formulary drug for the duration of the exigency.

(4) *Application of coverage appeals laws.* (i) A State may determine that a health plan in the State satisfies the requirements of this paragraph (c) if the health plan has a process to allow an enrollee to request and gain access to clinically appropriate drugs not otherwise covered by the health plan that is compliant with the State's applicable coverage appeals laws and regulations that are at least as stringent as the requirements of this paragraph (c) and include:

(A) An internal review;

(B) An external review;

(C) The ability to expedite the reviews; and

(D) Timeframes that are the same or shorter than the timeframes under paragraphs (c)(1)(ii), (c)(2)(iii), and (c)(3)(ii) of this section.

(ii) [Reserved]

(d)(1) For plan years beginning on or after January 1, 2016, a health plan must publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, the U.S. Office of Personnel Management, and the general public. A formulary drug list is easily accessible when:

(i) It can be viewed on the plan's public Web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and

(ii) If an issuer offers more than one plan, when an individual can easily discern which formulary drug list applies to which plan.

(2) A QHP in the Federally-facilitated Exchange must make available the information described in paragraph (d)(1) of this section on its Web site in an HHS-specified format and also submit this information to HHS, in a format and at times determined by HHS.

(e) For plan years beginning on or after January 1, 2017, a health plan providing essential health benefits must have the following access procedures:

(1) A health plan must allow enrollees to access prescription drug benefits at in-network retail pharmacies, unless:

(i) The drug is subject to restricted distribution by the U.S. Food and Drug Administration; or

(ii) The drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.

(2) A health plan may charge enrollees a different cost-sharing amount for obtaining a covered drug at a retail pharmacy, but all cost sharing will count towards the plan's annual limitation on cost sharing under §156.130 and must be accounted for in the plan's actuarial value calculated under §156.135.

(f) If a health plan covers prescription drugs in excess of the prescription drugs required to be covered under paragraph (a)(1) of this section, the additional prescription drugs are considered an essential health benefit and subject to requirements including the annual limitation on cost sharing and the restriction on annual and lifetime dollar limits, unless coverage of the drug is mandated by State action and is in addition to an essential health benefit pursuant to §155.170, in which case the drug would not be considered an essential health benefit.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 30350, May 27, 2014; 80 FR 10871, Feb. 27, 2015; 81 FR 12349, Mar. 8, 2016; 81 FR 53032, Aug. 11, 2016; 89 FR 26425, Apr. 15, 2024]

§ 156.125 Prohibition on discrimination.

(a) An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Beginning on the earlier of January 1, 2023 (the start of the 2023 plan

year) or upon renewal of any plan subject to this rule, a non-discriminatory benefit design that provides EHB is one that is clinically-based.

(b) An issuer providing EHB must comply with the requirements of §156.200(e) of this subchapter; and

(c) Nothing in this section shall be construed to prevent an issuer from appropriately utilizing reasonable medical management techniques.

[78 FR 12866, Feb. 25, 2013, as amended at 87 FR 27390, May 6, 2022]

§ 156.130 Cost-sharing requirements.

(a) *Annual limitation on cost sharing.* (1) For a plan year beginning in the calendar year 2014, cost sharing may not exceed the following:

(i) For self-only coverage—the annual dollar limit as described in section 223(c)(2)(A)(ii)(I) of the Internal Revenue Code of 1986 as amended, for self-only coverage that that is in effect for 2014; or

(ii) For other than self-only coverage—the annual dollar limit in section 223(c)(2)(A)(ii)(II) of the Internal Revenue Code of 1986 as amended, for non-self-only coverage that is in effect for 2014.

(2) For a plan year beginning in a calendar year after 2014, cost sharing may not exceed the following:

(i) For self-only coverage—the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage, as defined in paragraph (e) of this section.

(ii) For other than self-only coverage—twice the dollar limit for self-only coverage described in paragraph (a)(2)(i) of this section.

(b) [Reserved]

(c) *Special rule for network plans.* In the case of a plan using a network of providers, cost sharing paid by, or on behalf of, an enrollee for benefits provided outside of such network is not required to count toward the annual limitation on cost sharing (as defined in paragraph (a) of this section).

(d) *Increase annual dollar limits in multiples of 50.* For a plan year beginning in a calendar year after 2014, any increase in the annual dollar limits described in paragraph (a) of this section that does not result in a multiple of 50 dollars will be rounded down, to the next lowest multiple of 50 dollars.

(e) *Premium adjustment percentage.* The premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. HHS may publish the annual premium adjustment percentage in guidance in January of the calendar year preceding the benefit year for which the premium adjustment percentage is applicable, unless HHS proposes changes to the methodology, in which case, HHS will publish the annual premium adjustment percentage in an annual HHS notice of benefit and payment parameters or another appropriate rulemaking.

(f) *Coordination with preventive limits.* Nothing in this subpart is in derogation of the requirements of §147.130 of this subchapter.

(g) *Coverage of emergency department services.* Emergency department services must be provided as follows:

(1) Without imposing any requirement under the plan for prior authorization of services or any limitation on coverage where the provider of services is out of network that is more restrictive than the requirements or limitations that apply to emergency department services received in network; and

(2) If such services are provided out-of-network, cost-sharing must be limited as provided in §147.138(b)(3) of this subchapter.

(h) *Use of direct support offered by drug manufacturers.* Notwithstanding any other provision of this section, and to the extent consistent with State law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing, as defined in paragraph (a) of this section.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 30350, May 27, 2014; 80 FR 10872, Feb. 27, 2015; 84 FR 17567, Apr. 25, 2019; 85 FR 29261, May 14, 2020; 86 FR 24291, May 5, 2021]

§ 156.135 AV calculation for determining level of coverage.

(a) *Calculation of AV.* Subject to paragraphs (b) and (d) of this section, to calculate the AV of a health plan, the issuer must use the AV Calculator developed and made available by HHS for the given benefit year.

(b) *Exception to the use of the AV Calculator.* If a health plan's design is not compatible with the AV Calculator, the issuer must meet the following:

(1) Submit the actuarial certification from an actuary, who is a member of the American Academy of Actuaries, on the chosen methodology identified in paragraphs (b)(2) and (b)(3) of this section:

(2) Calculate the plan's AV by:

(i) Estimating a fit of its plan design into the parameters of the AV Calculator; and

(ii) Having an actuary, who is a member of the American Academy of Actuaries, certify that the plan design was fit appropriately in accordance with generally accepted actuarial principles and methodologies; or

(3) Use the AV Calculator to determine the AV for the plan provisions that fit within the calculator parameters and have an actuary, who is a member of the American Academy of Actuaries calculate and certify, in accordance with generally accepted actuarial principles and methodologies, appropriate adjustments to the AV identified by the calculator, for plan design features that deviate substantially from the parameters of the AV Calculator.

(4) The calculation methods described in paragraphs (b)(2) and (3) of this section may include only in-network cost-sharing, including multi-tier networks.

(c) *Employer contributions to health savings accounts and amounts made available under certain health reimbursement arrangements.* For plans other than those in the individual market that at the time of purchase are offered in conjunction with an HSA or with integrated HRAs that may be used only for cost-sharing, annual employer contributions to HSAs and amounts newly made available under such HRAs for the current year are:

(1) Counted towards the total anticipated medical spending of the standard population that is paid by the health plan; and

(2) Adjusted to reflect the expected spending for health care costs in a benefit year so that:

(i) Any current year HSA contributions are accounted for; and

(ii) The amounts newly made available under such integrated HRAs for the current year are accounted for.

(d) *Use of state-specific standard population for the calculation of AV.* Beginning in 2015, if submitted by the State and approved by HHS, a state-specific data set will be used as the standard population to calculate AV in accordance with paragraph (a) of this section. The data set may be approved by HHS if it is submitted in accordance with paragraph (e) of this section and:

(1) Supports the calculation of AVs for the full range of health plans available in the market;

(2) Is derived from a non-elderly population and estimates those likely to be covered by private health plans on or after January 1, 2014;

(3) Is large enough that: (i) The demographic and spending patterns are stable over time; and (ii) Includes a substantial majority of the State's insured population, subject to the requirement in paragraph (d)(2) of this section;

(4) Is a statistically reliable and stable basis for area-specific calculations; and (5) Contains claims data on health care services typically offered in the then-current market.

(e) *Submission of state-specific data.* AV will be calculated using the default standard population described in paragraph (f) of this section, unless a data set in a format specified by HHS that can support the use of the AV Calculator as described in paragraph (a) of this section is submitted by a State and approved by HHS consistent with paragraph (d) of this section by a date specified by HHS.

(f) *Default standard population.* The default standard population for AV calculation will be developed and summary statistics, such as in continuance tables, will be provided by HHS in a format that supports the calculation of

AV as described in paragraph (a) of this section.

(g) *Updates to the AV Calculator.* HHS will update the AV Calculator annually for material changes that may include costs, plan designs, the standard population, developments in the function and operation of the AV Calculator and other actuarially relevant factors.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 13839, Mar. 11, 2014; 81 FR 12349, Mar. 8, 2016]

§ 156.140 Levels of coverage.

(a) *General requirement for levels of coverage.* AV, calculated as described in § 156.135 of this subpart, and within a de minimis variation as defined in paragraph (c) of this section, determines whether a health plan offers a bronze, silver, gold, or platinum level of coverage.

(b) *The levels of coverage* are:

(1) *A bronze health plan* is a health plan that has an AV of 60 percent.

(2) *A silver health plan* is a health plan that has an AV of 70 percent.

(3) *A gold health plan* is a health plan that has an AV of 80 percent.

(4) *A platinum health plan* is a health plan that has as an AV of 90 percent.

(c) *De minimis variation.* (1) For plan years beginning on or after January 1, 2018 through December 31, 2022, the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is −4 percentage points and +2 percentage points, except if a health plan under paragraph (b)(1) of this section (a bronze health plan) either covers and pays for at least one major service, other than preventive services, before the deductible or meets the requirements to be a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, in which case the allowable variation in AV for such plan is −4 percentage points and +5 percentage points.

(2) For plan years beginning on or after January 1, 2023, the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is −2 percentage points and +2 percentage points, except if a health plan under paragraph (b)(1) of this section (a bronze health plan) either covers and pays for at least one major service, other than preventive services, before the deductible or meets the requirements to be a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, in which case the allowable variation in AV for such plan is −2 percentage points and +5 percentage points.

[78 FR 12866, Feb. 25, 2013, as amended at 81 FR 94180, Dec. 22, 2016; 82 FR 18382, Apr. 18, 2017; 87 FR 27390, May 6, 2022]

§ 156.145 Determination of minimum value.

(a) *Acceptable methods for determining MV.* An employer-sponsored plan provides minimum value (MV) only if the percentage of the total allowed costs of benefits provided under the plan is greater than or equal to 60 percent, and the benefits under the plan include substantial coverage of inpatient hospital services and physician services. An employer-sponsored plan may use one of the following methods to determine whether the percentage of the total allowed costs of benefits provided under the plan is not less than 60 percent.

(1) The MV Calculator to be made available by HHS and the Internal Revenue Service. The result derived from the calculator may be modified under the rules in paragraph (b) of this section.

(2) Any safe harbor established by HHS and the Internal Revenue Service.

(3) A group health plan may seek certification by an actuary to determine MV if the plan contains non-standard features that are not suitable for either of the methods described in paragraphs (a)(1) or (2) of this section. The determination of MV must be made by a member of the American Academy of Actuaries, based on an analysis performed in accordance with generally accepted actuarial principles and methodologies.

(4) Any plan in the small group market that meets any of the levels of coverage, as described in § 156.140 of this subpart, satisfies minimum value.

(b) *Benefits that may be counted towards the determination of MV.* (1) In the event that a group health plan uses the

MV Calculator and offers an EHB outside of the parameters of the MV Calculator, the plan may seek an actuary, who is a member of the American Academy of Actuaries, to determine the value of that benefit and adjust the result derived from the MV Calculator to reflect that value.

(2) For the purposes of applying the options described in paragraph (a) of this section in determining MV, a group health plan will be permitted to take into account all benefits provided by the plan that are included in any one of the EHB-benchmarks.

(c) *Standard population.* The standard population for MV determinations described in paragraph (a) of this section is the standard population developed by HHS for such use and described through summary statistics issued by HHS. The standard population for MV must reflect the population covered by self-insured group health plans.

(d) *Employer contributions to health savings accounts and amounts made available under certain health reimbursement arrangements.* For employer-sponsored self-insured group health plans and insured group health plans that at the time of purchase are offered in conjunction with an HSA or with integrated HRAs that may be used only for cost-sharing, annual employer contributions to HSAs and amounts newly made available under such HRAs for the current year are:

(1) Counted towards the total anticipated medical spending of the standard population that is paid by the health plan; and

(2) Adjusted to reflect the expected spending for health care costs in a benefit year so that:

(i) Any current year HSA contributions are accounted for; and

(ii) The amounts newly made available under such integrated HRAs for the current year are accounted for.

[78 FR 12866, Feb. 25, 2013, as amended at 80 FR 10872, Feb. 27, 2015]

§ 156.150 Application to stand-alone dental plans inside the Exchange.

(a) *Annual limitation on cost-sharing.* For a stand-alone dental plan covering the pediatric dental EHB under § 155.1065 of this subchapter in any Exchange, cost sharing may not exceed $350 for one covered child and $700 for two or more covered children.

(1) For plan years beginning after 2017, for one covered child—the dollar limit applicable to a stand-alone dental plan for one covered child specified in this paragraph (a) increased by the percent increase of the consumer price index for dental services for the year 2 years prior to the applicable plan year over the consumer price index for dental services for 2016.

(2) For plan years after 2017, for two or more covered children—twice the dollar limit for one child described in paragraph (a)(1) of this section.

(b) *Calculation of AV.* A stand-alone dental plan:

(1) May not use the AV calculator in § 156.135; and

(2) Must have the plan's actuarial value of coverage for pediatric dental essential health benefits certified by a member of the American Academy of Actuaries using generally accepted actuarial principles and reported to the Exchange.

(c) *Consumer price index for dental services defined.* The consumer price index for dental services is a sub-component of the U.S. Department of Labor's Bureau of Labor Statistics Consumer Price Index specific to dental services.

(d) *Increments of cost sharing increases.* Any increase in the annual dollar limits described in paragraph (a)(1) of this section that does not result in a multiple of 25 dollars will be rounded down, to the next lowest multiple of 25 dollars.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 13840, Mar. 11, 2014; 81 FR 12349, Mar. 8, 2016; 83 FR 17069, Apr. 17, 2018]

§ 156.155 Enrollment in catastrophic plans.

(a) *General rule.* A health plan is a catastrophic plan if it meets the following conditions:

(1) Meets all applicable requirements for health insurance coverage in the individual market (including but not limited to those requirements described in parts 147 and 148 of this subchapter), and is offered only in the individual market.

(2) Does not provide a bronze, silver, gold, or platinum level of coverage described in section 1302(d) of the Affordable Care Act.

(3) Provides coverage of the essential health benefits under section 1302(b) of the Affordable Care Act, except that the plan provides no benefits for any plan year (except as provided in paragraphs (a)(4), (b), and (c) of this section) until the annual limitation on cost sharing in section 1302(c)(1) of the Affordable Care Act is reached.

(4) Provides coverage for at least three primary care visits per year before reaching the deductible.

(5) Covers only individuals who meet either of the following conditions:

(i) Have not attained the age of 30 prior to the first day of the plan or policy year.

(ii) Have received a certificate of exemption for the reasons identified in section 1302(e)(2)(B)(i) or (ii) of the Affordable Care Act.

(b) *Coverage of preventive health services.* A catastrophic plan may not impose any cost-sharing requirements (such as a copayment, coinsurance, or deductible) for preventive services, in accordance with section 2713 of the Public Health Service Act.

(c) *Coverage to prevent surprise medical bills.* A catastrophic plan must provide benefits as required under sections 2799A–1 and 2799A–2 of the Public Health Service Act and their implementing regulations in §§149.110, 149.120, and 149.130 or any applicable State law providing similar protections to individuals, and will not violate paragraph (a)(3) of this section solely because of the provision of such benefits before the annual limitation on cost sharing is reached.

(d) *Application for family coverage.* For other than self-only coverage, each individual enrolled must meet the requirements of paragraph (a)(5) of this section.

[78 FR 13442, Feb. 27, 2013, as amended at 78 FR 65096, Oct. 30, 2013; 86 FR 36985, July 13, 2021]

Subpart C—Qualified Health Plan Minimum Certification Standards

SOURCE: 77 FR 18469, Mar. 27, 2012, unless otherwise noted.

§ 156.200 QHP issuer participation standards.

(a) *General requirement.* In order to participate in an Exchange, a health insurance issuer must have in effect a certification issued or recognized by the Exchange to demonstrate that each health plan it offers in the Exchange is a QHP.

(b) *QHP issuer requirement.* A QHP issuer must—

(1) Comply with the requirements of this subpart with respect to each of its QHPs on an ongoing basis;

(2) Comply with Exchange processes, procedures, and requirements set forth in accordance with subpart K of part 155 of this subchapter and, in the small group market, §§155.705 and 155.706 of this subchapter;

(3) Ensure that each QHP complies with benefit design standards, as defined in §156.20, except that individual market silver QHPs must have an AV of 70 percent, with a *de minimis* allowable AV variation of −0 percentage points and +2 percentage points;

(4) Be licensed and in good standing to offer health insurance coverage in each State in which the issuer offers health insurance coverage;

(5) Implement and report on a quality improvement strategy or strategies described in section 1311(c)(1)(E) of the Affordable Care Act consistent with the standards of section 1311(g) of the Affordable Care Act, disclose and report information on health care quality and outcomes described in sections 1311(c)(1)(H), (c)(1)(I), and (c)(3) of the Affordable Care Act, and implement appropriate enrollee satisfaction surveys consistent with section 1311(c)(4) of the Affordable Care Act

(6) Pay any applicable user fees assessed under §156.50; and

(7) Comply with the standards under 45 CFR part 153.

(c) *Offering requirements.* A QHP issuer must offer through the Exchange:

(1) At least one QHP in the silver coverage level and at least one QHP in the gold coverage level as described in §156.140 throughout each service area in which it offers coverage through the Exchange; and,

(2) A child-only plan at the same level of coverage, as described in section 1302(d)(1) of the Affordable Care Act, as any QHP offered through the Exchange to individuals who, as of the beginning of the plan year, have not attained the age of 21.

(d) *State requirements.* A QHP issuer certified by an Exchange must adhere to the requirements of this subpart and any provisions imposed by the Exchange, or a State in connection with its Exchange, that are conditions of participation or certification with respect to each of its QHPs.

(e) *Non-discrimination.* A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).

(f) *Broker compensation in a Federally-facilitated Exchange.* A QHP issuer must pay the same broker compensation for QHPs offered through a Federally-facilitated Exchange that the QHP issuer pays for similar health plans offered in the State outside a Federally-facilitated Exchange.

(g) *Certification standard specific to a Federally-facilitated Exchange for plan years beginning before January 1, 2018.* A Federally-facilitated Exchange may certify a QHP in the individual market of a Federally-facilitated Exchange only if the QHP issuer meets one of the conditions below:

(1) The QHP issuer also offers through a Federally-facilitated SHOP serving that State at least one small group market QHP at the silver level of coverage and one at the gold level of coverage as described in section 1302(d) of the Affordable Care Act;

(2) The QHP issuer does not offer small group market products in that State, but another issuer in the same issuer group offers through a Federally-facilitated SHOP serving that State at least one small group market QHP at the silver level of coverage and one at the gold level of coverage; or

(3) Neither the issuer nor any other issuer in the same issuer group has a share of the small group market, as determined by HHS, greater than 20 percent, based on the earned premiums submitted by all issuers in the State's small group market, under §158.110 of this subchapter, on the reporting date immediately preceding the due date of the application for QHP certification.

(h) *Operational requirements.* As a condition of certification of a QHP, an issuer must attest that it will comply with all QHP operational requirements described in subparts D, E, H, K, L, and M of this part.

[77 FR 18469, Mar. 27, 2012, as amended at 78 FR 15535, Mar. 11, 2013; 79 FR 30351, May 27, 2014; 80 FR 10873, Feb. 27, 2015; 81 FR 94181, Dec. 22, 2016; 83 FR 17069, Apr. 17, 2018; 85 FR 37248, June 19, 2020; 87 FR 27391, May 6, 2022; 89 FR 37703, May 6, 2024]

§ 156.201 Standardized plan options.

A qualified health plan (QHP) issuer in a Federally-facilitated Exchange or a State-based Exchange on the Federal platform, other than an issuer that is already required to offer standardized plan options under State action taking place on or before January 1, 2020, must:

(a) For the plan year 2023, offer in the individual market at least one standardized QHP option, defined at §155.20 of this subchapter, at every product network type, as the term is described in the definition of ''product'' at §144.103 of this subchapter, at every metal level, and throughout every service area that it also offers non-standardized QHP options, including, for silver plans, for the income-based cost-sharing reduction plan variations, as provided for at §156.420(a); and

(b) For plan year 2024 and subsequent plan years, offer in the individual market at least one standardized QHP option, defined at §155.20 of this subchapter, at every product network type, as the term is described in the definition of ''product'' at §144.103 of this subchapter, at every metal level except the non-expanded bronze metal level, and throughout every service area that it also offers non-standardized QHP options, including, for silver plans, for the income-based cost-sharing reduction plan variations, as provided for at §156.420(a).

[88 FR 25921, Apr. 27, 2023]

§ 156.202 Non-standardized plan option limits.

A QHP issuer in a Federally-facilitated Exchange or a State-based Exchange on the Federal platform:

(a) For plan year 2024, is limited to offering four non-standardized plan options per product network type, as the term is described in the definition of ''product'' at §144.103 of this subchapter, metal level (excluding catastrophic plans), and inclusion of dental and/or vision benefit coverage (as defined in paragraph (c) of this section), in any service area.

(b) For plan year 2025 and subsequent plan years, is limited to offering two non-standardized plan options per product network type, as the term is described in the definition of ''product'' at §144.103 of this subchapter, metal level (excluding catastrophic plans), and inclusion of dental and/or vision benefit coverage (as defined in paragraph (c) of this section), in any service area.

(c) For purposes of paragraphs (a) and (b) of this section, the inclusion of dental and/or vision benefit coverage is defined as coverage of any or all of the following:

(1) Adult dental benefit coverage as defined by the following in the ''Benefits'' column in the Plans and Benefits Template:

(i) Routine Dental Services (Adult);

(ii) Basic Dental Care—Adult; or

(iii) Major Dental Care—Adult.

(2) Pediatric dental benefit coverage as defined by the following in the ''Benefits'' column in the Plans and Benefits Template:

(i) Dental Check-Up for Children;

(ii) Basic Dental Care—Child; or

(iii) Major Dental Care—Child.

(3) Adult vision benefit coverage as defined by the following in the ''Benefits'' column in the Plans and Benefits Template: Routine Eye Exam (Adult).

(d) For plan year 2025 and subsequent years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area if it demonstrates that these additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in an issuer's other non-standardized plan option offerings in the same product network type, metal level, and service area.

(1) The 25 percent reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions will be evaluated at the level of total out-of-pocket costs for the treatment of the chronic and high-cost condition for a population of enrollees with the relevant chronic and high-cost condition.

(2) The reduction in cost sharing must not be limited to a part of the year, or an otherwise limited scope of benefits.

(3) The reduction in cost sharing for these benefits cannot be conditioned on a consumer having a particular diagnosis.

(4) The required reduction in cost sharing only applies to the standard variant of the plan for which an issuer seeks an exception, and not to the income-based cost-sharing reduction plan variations required by §156.420(a), nor to the zero and limited cost-sharing plan variations required by §156.420(b).

(5) Issuers are limited to one exception per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area, for each chronic and high-cost condition.

(6) Chronic and high-cost conditions that may qualify an issuer for this exception will be determined by HHS.

(e) An issuer that seeks to utilize this exceptions process is required to submit a written justification in a form and manner and at a time prescribed by HHS that:

(1) Identifies the specific chronic and high-cost condition that its additional non-standardized plan option offers substantially reduced cost sharing for, in accordance with the definition of ''cost sharing'' at §156.20;

(2) Identifies which benefits in the Plans and Benefits Template are discounted to provide reduced treatment-specific cost sharing for individuals with the specified chronic and high-

cost condition. These discounts must be relative to the treatment-specific cost sharing for the same corresponding benefits in the issuer's other non-standardized plan offerings in the same product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area. For the purposes of this standard, treatment specific cost sharing consists of the costs for obtaining services that pertain to the treatment of a particular chronic and high-cost condition—but not the costs for obtaining services that do not pertain to the treatment of the relevant condition. The issuer must identify all services for which the benefits substantially reduce cost sharing in the Plans and Benefits Template. These benefits must encompass a complete list of relevant services pertaining to the treatment of the relevant condition;

(3) Explains how the reduced cost sharing for these services pertains to clinically indicated guidelines and a representative treatment scenario for treatment of the specified chronic and high-cost condition (and include any relevant studies, guidelines, or supplementary documents to support the application, as applicable). For the purposes of this standard, a representative treatment scenario is an annual course of treatment for a chronic and high-cost condition; and

(4) Includes a corresponding actuarial memorandum that explains the underlying actuarial assumptions made in the design of the plan the issuer is requesting to except. In this memorandum, an issuer must demonstrate how the benefits that are discounted to provide reduced treatment-specific cost sharing of at least 25 percent identified at §156.202(e)(2) for the treatment of the condition identified at §156.202(e)(1) under the excepted plan compare to the identified in-limit offering in the same product network type, metal level, inclusion of dental and/or vision coverage, and service area. This demonstration must specifically be in reference to the specific population that would be seeking treatment for the relevant condition and not the general population. This memorandum must also include an actuarial opinion confirming that this analysis was prepared in accordance with the appropriate Actuarial Standards of Practice and the profession's Code of Professional Conduct.

[88 FR 25922, Apr. 27, 2023, as amended at 89 FR 26425, Apr. 15, 2024]

§156.210 QHP rate and benefit information.

(a) *General rate requirement.* A QHP issuer must set rates for an entire benefit year, or for the SHOP, plan year.

(b) *Rate and benefit submission.* A QHP issuer must submit rate and benefit information to the Exchange.

(c) *Rate justification.* A QHP issuer must submit to the Exchange a justification for a rate increase prior to the implementation of the increase. A QHP issuer must prominently post the justification on its Web site.

(d) *Rate requirements* for *stand-alone dental plans.* For benefit and plan years beginning on or after January 1, 2024:

(1) *Age on effective date.* The premium rate charged by an issuer of stand-alone dental plans may vary with respect to the particular plan or coverage involved by determining the enrollee's age. Any age calculation for rating and eligibility purposes must be based on the age as of the time of policy issuance or renewal.

(2) *Guaranteed rates.* An issuer of stand-alone dental plans must set guaranteed rates.

[77 FR 18469, Mar. 27, 2012, as amended at 88 FR 25922, Apr. 27, 2023]

§156.215 Advance payments of the premium tax credit and cost-sharing reduction standards.

(a) *Standards relative to advance payments of the premium tax credit and cost-sharing reductions.* In order for a health plan to be certified as a QHP initially and to maintain certification to be offered in the individual market on the Exchange, the issuer must meet the requirements related to the administration of cost-sharing reductions and advance payments of the premium tax credit set forth in subpart E of this part.

(b) [Reserved]

[78 FR 15535, Mar. 11, 2013]

§ 156.220 Transparency in coverage.

(a) *Required information.* A QHP issuer must provide the following information in accordance with the standards in paragraph (b) of this section:

(1) Claims payment policies and practices;

(2) Periodic financial disclosures;

(3) Data on enrollment;

(4) Data on disenrollment;

(5) Data on the number of claims that are denied;

(6) Data on rating practices;

(7) Information on cost-sharing and payments with respect to any out-of-network coverage; and

(8) Information on enrollee rights under title I of the Affordable Care Act.

(b) *Reporting requirement.* A QHP issuer must submit, in an accurate and timely manner, to be determined by HHS, the information described in paragraph (a) of this section to the Exchange, HHS and the State insurance commissioner, and make the information described in paragraph (a) of this section available to the public.

(c) *Use of plain language.* A QHP issuer must make sure that the information submitted under paragraph (b) is provided in plain language as defined under § 155.20 of this subtitle.

(d) *Enrollee cost sharing transparency.* A QHP issuer must make available the amount of enrollee cost sharing under the individual's plan or coverage with respect to the furnishing of a specific item or service by a participating provider in a timely manner upon the request of the individual. At a minimum, such information must be made available to such individual through an Internet Web site and such other means for individuals without access to the Internet.

§ 156.221 Access to and exchange of health data and plan information.

(a) *Application Programming Interface to support enrollees.* Subject to paragraph (h) of this section, a QHP issuer on a Federally-Facilitated Exchange must implement and maintain a standards-based Application Programming Interface (API) that permits third-party applications to retrieve, with the approval and at the direction of a current individual enrollee or the enrollee's personal representative, data specified in paragraph (b) of this section through the use of common technologies and without special effort from the enrollee.

(b) *Accessible content.* (1) A QHP issuer on a Federally-facilitate Exchange must make the following information accessible to its current enrollees or the enrollee's personal representative through the API described in paragraph (a) of this section:

(i) Data concerning adjudicated claims, including claims data for payment decisions that may be appealed, were appealed, or are in the process of appeal, and provider remittances and enrollee cost-sharing pertaining to such claims, no later than one (1) business day after a claim is processed;

(ii) Encounter data from capitated providers, no later than one (1) business day after data concerning the encounter is received by the QHP issuer;

(iii) All data classes and data elements included in a content standard in 45 CFR 170.213 that are maintained by the Qualified Health Plan (QHP) issuer no later than 1 business day after the QHP issuer receives the data; and

(iv) For plan years beginning on or after January 1, 2027, the information in paragraph (b)(1)(iv)(A) of this section about prior authorizations for items and services (excluding drugs, as defined in paragraph (b)(1)(v) of this section), according to the timelines in paragraph (b)(1)(iv)(B) of this section.

(A) The prior authorization request and decision, including all of the following, as applicable:

(*1*) The prior authorization status.

(*2*) The date the prior authorization was approved or denied.

(*3*) The date or circumstance under which the prior authorization ends.

(*4*) The items and services approved.

(*5*) If denied, a specific reason why the request was denied.

(*6*) Related structured administrative and clinical documentation submitted by a provider.

(B) The information in paragraph (b)(1)(iv)(A) of this section must—

(*1*) Be accessible no later than 1 business day after the QHP issuer receives a prior authorization request;

(*2*) Be updated no later than 1 business day after any status change; and

(*3*) Continue to be accessible for the duration that the authorization is active and at least 1 year after the prior authorization's last status change.

(v) Drugs are defined for the purposes of paragraph (b)(1)(iv) of this section as any and all drugs covered by the QHP issuer.

(2) [Reserved]

(c) *Technical requirements.* A QHP issuer on a Federally-facilitated Exchange implementing an API under paragraph (a) of this section:

(1) Must implement and maintain API technology conformant with 45 CFR 170.215(a)(1), (b)(1)(i), (c)(1), and (e)(1);

(2) Must conduct routine testing and monitoring, and update as appropriate, to ensure the API functions properly, including assessments to verify the API is fully and successfully implementing privacy and security features such as, but not limited to, those required to comply with HIPAA privacy and security requirements in parts 160 and 164, 42 CFR parts 2 and 3, and other applicable law protecting privacy and security of individually identifiable data;

(3) Must comply with the content and vocabulary standard requirements in paragraphs (c)(3)(i) and (ii) of this section, as applicable, to the data type or data element, unless alternate standards are required by other applicable law:

(i) Content and vocabulary standards at 45 CFR 170.213 where such are applicable to the data type or element, as appropriate; and

(ii) Content and vocabulary standards at part 162 of this subchapter and 42 CFR 423.160 where required by law, or where such standards are applicable to the data type or element, as appropriate.

(4) May use an updated version of any standard or all standards required under paragraphs (c)(1) or (3) of this section, where:

(i) Use of the updated version of the standard is required by other applicable law, or

(ii) Use of the updated version of the standard is not prohibited under other applicable law, provided that:

(A) For content and vocabulary standards other than those at 45 CFR 170.213, the Secretary has not prohibited use of the updated version of a standard for purposes of this section or part 170 of this subchapter;

(B) For standards at 45 CFR 170.213 and 45 CFR 170.215, the National Coordinator has approved the updated version for use in the ONC Health IT Certification Program; and

(C) Using the updated version of the standard, implementation guide, or specification does not disrupt an end user's ability to access the data specified in paragraph (b) of this section or §§ 156.221, 156.222, and 156.223 through the required APIs.

(d) *Documentation requirements for APIs.* For each API implemented in accordance with paragraph (a) of this section, a QHP issuer on a Federally-Facilitated Exchange must make publicly accessible, by posting directly on its website and/or via publicly accessible hyperlink(s), complete accompanying documentation that contains, at a minimum the information listed in this paragraph. For the purposes of this section, ''publicly accessible'' means that any person using commonly available technology to browse the internet could access the information without any preconditions or additional steps, such as a fee for access to the documentation; a requirement to receive a copy of the material via email; a requirement to register or create an account to receive the documentation; or a requirement to read promotional material or agree to receive future communications from the organization making the documentation available;

(1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns;

(2) The software components and configurations an application must use in order to successfully interact with the API and process its response(s); and

(3) All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API.

(e) *Denial or discontinuation of access to the API.* A QHP issuer on a Federally-Facilitated Exchange may deny or discontinue any third party application's connection to the API required under paragraph (a) of this section if the QHP issuer:

(1) Reasonably determines, consistent with its security risk analysis under 45 CFR part 164 subpart C, that allowing an application to connect or remain connected to the API would present an unacceptable level of risk to the security of personally identifiable information, including protected health information, on the QHP issuer's systems; and

(2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all apps and developers through which parties seek to access electronic health information, as defined in 45 CFR 171.102, including but not limited to criteria that rely on automated monitoring and risk mitigation tools.

(f) *Reporting on Patient Access API usage.* Beginning in 2026, by March 31 following any calendar year that it offers a QHP on a Federally-facilitated Exchange, a QHP issuer must report to CMS the following metrics, in the form of aggregated, de-identified data, for the previous calendar year at the issuer level in the form and manner specified by the Secretary:

(1) The total number of unique enrollees whose data are transferred via the Patient Access API to a health app designated by the enrollee.

(2) The total number of unique enrollees whose data are transferred more than once via the Patient Access API to a health app designated by the enrollee.

(g) *Enrollee resources regarding privacy and security.* A QHP issuer on a Federally-facilitated Exchange must provide in an easily accessible location on its public website and through other appropriate mechanisms through which it ordinarily communicates with current and former enrollees seeking to access their health information held by the QHP issuer, educational resources in non-technical, simple and easy-to-understand language explaining at a minimum:

(1) General information on steps the individual may consider taking to help protect the privacy and security of their health information, including factors to consider in selecting an application including secondary uses of data, and the importance of understanding the security and privacy practices of any application to which they will entrust their health information; and

(2) An overview of which types of organizations or individuals are and are not likely to be HIPAA covered entities, the oversight responsibilities of the Office for Civil Rights (OCR) and the Federal Trade Commission (FTC), and how to submit a complaint to:

(i) The HHS Office for Civil Rights (OCR); and

(ii) The Federal Trade Commission (FTC).

(h) *Exception.* (1) If a plan applying for QHP certification to be offered through a Federally-facilitated Exchange believes it cannot satisfy the requirements in paragraphs (a) through (g) of this section, the issuer must include as part of its QHP application a narrative justification describing the reasons why the plan cannot reasonably satisfy the requirements for the applicable plan year, the impact of non-compliance upon enrollees, the current or proposed means of providing health information to enrollees, and solutions and a timeline to achieve compliance with the requirements of this section.

(2) The Federally-facilitated Exchange may grant an exception to the requirements in paragraphs (a) through (g) of this section if the Exchange determines that making such health plan available through such Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates.

(i) *Applicability.* A QHP issuer on an individual market Federally-facilitated Exchange, not including QHP issuers offering only stand-alone dental plans, must comply with the requirements in paragraphs (a) through (e) and (g) of this section beginning with plan years beginning on or after January 1, 2021, and with the requirements in paragraph (f) of this section beginning in 2026, with regard to data:

(1) With a date of service on or after January 1, 2016; and

(2) That are maintained by the QHP issuer for enrollees in QHPs.

[85 FR 25638, May 1, 2020, as amended at 89 FR 8986, Feb. 8, 2024]

§ 156.222 Access to and exchange of health data for providers and payers.

(a) *Application programming interface to support data exchange from payers to providers—Provider Access API.* Unless granted an exception under paragraph (c) of this section, for plan years beginning on or after January 1, 2027, QHP issuers on a Federally-facilitated Exchange must do the following:

(1) *API requirements.* Implement and maintain an application programming interface (API) conformant with all of the following:

(i) Section 156.221(c)(2) through (4), (d), and (e).

(ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), (c)(1), and (d)(1).

(2) *Provider access.* Make the data specified in §156.221(b) with a date of service on or after January 1, 2016, excluding provider remittances and enrollee cost-sharing information, that are maintained by the QHP issuer to available in-network providers via the API required in paragraph (a)(1) of this section no later than 1 business day after receiving a request from such a provider, if all the following conditions are met:

(i) The QHP issuer authenticates the identity of the provider that requests access and attributes the enrollee to the provider under the attribution process described in paragraph (a)(3) of this section.

(ii) The enrollee does not opt out as described in paragraph (a)(4) of this section.

(iii) Disclosure of the data is not prohibited by other applicable law.

(3) *Attribution.* Establish and maintain a process to associate enrollees with their in-network providers to enable data exchange via the Provider Access API.

(4) *Opt out and patient educational resources.* (i) Establish and maintain a process to allow an enrollee or the enrollee's personal representative to opt out of data exchange described in paragraph (a)(2) of this section and to change their permission at any time. That process must be available before the first date on which the QHP issuer makes enrollee information available via the Provider Access API and at any time while the enrollee is enrolled with the QHP issuer.

(ii) Provide information to enrollees in plain language about the benefits of API data exchange with their providers, their opt out rights, and instructions both for opting out of data exchange and for subsequently opting in, as follows:

(A) Before the first date on which the QHP issuer makes enrollee information available through the Provider Access API.

(B) No later than 1 week after the after the coverage start date or no later than 1 week after the effectuation of coverage, whichever is later.

(C) At least annually.

(D) In an easily accessible location on its public website.

(5) *Provider resources.* Provide on its website and through other appropriate provider communications, information in plain language explaining the process for requesting enrollee data using the Provider Access API required in paragraph (a)(1) of this section. The resources must include information about how to use the QHP issuer's attribution process to associate enrollees with their providers.

(b) *Application programming interface to support data exchange between payers—Payer-to-Payer API.* Unless granted an exception under paragraph (c) of this section, for plan years beginning on or after January 1, 2027, QHP issuers on a Federally-facilitated Exchange must do the following:

(1) *API requirements.* Implement and maintain an API conformant with all of the following:

(i) Section 156.221(c)(2) through (4), (d), and (e).

(ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (d)(1).

(2) *Opt in.* Establish and maintain a process to allow enrollees or their personal representatives to opt into the QHP issuer's payer to payer data exchange with the enrollee's previous payer(s), described in paragraphs (b)(4)

and (5) of this section, and with concurrent payer(s), described in paragraph (b)(6) of this section, and to change their permission at any time.

(i) The opt in process must be offered as follows:

(A) To current enrollees, no later than the compliance date.

(B) To new enrollees, no later than 1 week after the coverage start date or no later than 1 week after the effectuation of coverage, whichever is later.

(ii) If an enrollee does not respond or additional information is necessary, the QHP issuer must make reasonable efforts to engage with the enrollee to collect this information.

(3) *Identify previous and concurrent payers.* Establish and maintain a process to identify a new enrollee's previous and concurrent payer(s) to facilitate the Payer-to-Payer API data exchange. The information request process must start as follows:

(i) For current enrollees, no later than the compliance date.

(ii) For new enrollees, no later than 1 week after the coverage start date or no later than 1 week after the effectuation of coverage, whichever is later.

(iii) If an enrollee does not respond or additional information is necessary, the QHP issuer must make reasonable efforts to engage with the enrollee to collect this information.

(4) *Exchange request requirements.* Exchange enrollee data with other payers, consistent with the following requirements:

(i) The QHP issuer must request the data specified in paragraph (b)(4)(ii) of this section through the enrollee's previous payers' API, if all the following conditions are met:

(A) The enrollee has opted in, as described in paragraph (b)(2) of this section.

(B) The exchange is not prohibited by other applicable law.

(ii) The data to be requested are all of the following with a date of service within 5 years before the request:

(A) Data specified in §156.221(b) excluding the following:

(*1*) Provider remittances and enrollee cost-sharing information.

(*2*) Denied prior authorizations.

(B) Unstructured administrative and clinical documentation submitted by a provider related to prior authorizations.

(iii) The QHP issuer must include an attestation with this request affirming that the enrollee is enrolled with the QHP issuer and has opted into the data exchange.

(iv) The QHP issuer must complete this request as follows:

(A) No later than 1 week after the payer has sufficient identifying information about previous payers and the enrollee has opted in.

(B) At an enrollee's request, within 1 week of the request.

(v) The QHP issuer must receive, through the API required in paragraph (b)(1) of this section, and incorporate into its records about the enrollee, any data made available by other payers in response to the request.

(5) *Exchange response requirements.* Make available the data specified in paragraph (b)(4)(ii) of this section that are maintained by the QHP issuer to other payers via the API required in paragraph (b)(1) of this section within 1 business day of receiving a request, if all the following conditions are met:

(i) The payer that requests access has its identity authenticated and includes an attestation with the request that the patient is enrolled with the payer and has opted into the data exchange.

(ii) Disclosure of the data is not prohibited by other applicable law.

(6) *Concurrent coverage data exchange requirements.* When an enrollee has provided sufficient identifying information about concurrent payers and has opted in as described in paragraph (b)(2) of this section, a QHP issuer on a Federally-facilitated Exchange must do the following, through the API required in paragraph (b)(1) of this section:

(i) Request the enrollee's data from all known concurrent payers as described in paragraph (b)(4) of this section, and at least quarterly thereafter while the enrollee is enrolled with both payers.

(ii) Respond as described in paragraph (b)(5) of this section within 1 business day of a request from any concurrent payers. If agreed upon with the requesting payer, the QHP issuer may exclude any data that were previously

sent to or originally received from the concurrent payer.

(7) *Patient educational resources.* Provide information to enrollees in plain language, explaining at a minimum: the benefits of Payer-to-Payer API data exchange, their ability to opt in or withdraw that permission, and instructions for doing so. The QHP issuer must provide the following resources:

(i) When requesting an enrollee's permission for Payer-to-Payer API data exchange, as described in paragraph (b)(2) of this section.

(ii) At least annually, in appropriate mechanisms through which it ordinarily communicates with current enrollees.

(iii) In an easily accessible location on its public website.

(c) *Exception.* (1) If a plan applying for QHP certification to be offered through a Federally-facilitated Exchange believes it cannot satisfy the requirements in paragraph (a) or (b) (or paragraphs (a) and (b)) of this section, the issuer must include a narrative justification in its QHP application that describes all of the following:

(i) The reasons why the issuer cannot reasonably satisfy the requirements for the applicable plan year.

(ii) The impact of non-compliance upon providers and enrollees.

(iii) The current or proposed means of providing health information to payers.

(iv) Solutions and a timeline to achieve compliance with the requirements in paragraph (a) or (b) of this section (or paragraphs (a) and (b)).

(2) The Federally-facilitated Exchange may grant an exception to the requirements in paragraph (a) or (b) (or paragraphs (a) and (b)) of this section if the Exchange determines that making QHPs of such issuer available through such Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates, and an exception is warranted to permit the issuer to offer QHPs through the FFE.

[89 FR 8986, Feb. 8, 2024]

§ 156.223 Prior authorization requirements.

(a) *Communicating a reason for denial.* Beginning January 1, 2026, if the QHP issuer denies a prior authorization request (excluding a request for coverage of drugs as defined in § 156.221(b)(1)(v)), the response to the provider must include a specific reason for the denial, regardless of the method used to communicate that information.

(b) *Prior Authorization Application Programming Interface (API).* Unless granted an exception under paragraph (d) of this section, for plan years beginning on or after January 1, 2027, a QHP issuer on a Federally-facilitated Exchange must implement and maintain an API conformant with § 156.221(c)(2) through (4), (d), and (e), and the standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (c)(1) that—

(1) Is populated with the QHP issuer's list of covered items and services (excluding drugs as defined in § 156.221(b)(1)(v)) that require prior authorization;

(2) Can identify all documentation required by the QHP issuer for approval of any items or services that require prior authorization;

(3) Supports a HIPAA-compliant prior authorization request and response, as described in 45 CFR part 162; and

(4) Communicates the following information about prior authorization requests:

(i) Whether the QHP issuer—

(A) Approves the prior authorization request (and the date or circumstance under which the authorization ends);

(B) Denies the prior authorization request; or

(C) Requests more information.

(ii) If the QHP issuer denies the prior authorization request, it must include a specific reason for the denial.

(c) *Publicly reporting prior authorization metrics.* Beginning in 2026, following each year it offers a QHP on a Federally-facilitated Exchange, a QHP issuer must report prior authorization data, excluding data on drugs as defined in § 156.221(b)(1)(v), at the issuer level by March 31. The QHP issuer must make the following data from the previous calendar year publicly accessible by posting them on its website:

(1) A list of all items and services that require prior authorization.

(2) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.

(3) The percentage of standard prior authorization requests that were denied, aggregated for all items and services.

(4) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.

(5) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.

(6) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.

(7) The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.

(8) The average and median time that elapsed between the submission of a request and a determination by the QHP issuer, for standard prior authorizations, aggregated for all items and services.

(9) The average and median time that elapsed between the submission of a request and a decision by the QHP issuer for expedited prior authorizations, aggregated for all items and services.

(d) *Exception.* (1) If a plan applying for QHP certification to be offered through a Federally-facilitated Exchange believes it cannot satisfy the requirements in paragraph (b) of this section, the issuer must include a narrative justification in its QHP application that describes all of the following:

(i) The reasons why the issuer cannot reasonably satisfy the requirements for the applicable plan year.

(ii) The impact of non-compliance upon providers and enrollees.

(iii) The current or proposed means of providing health information to providers.

(iv) Solutions and a timeline to achieve compliance with the requirements in paragraph (b) of this section.

(2) The Federally-facilitated Exchange (FFE) may grant an exception to the requirements in paragraph (b) of this section if the Exchange determines that making QHPs of such issuer available through such Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates and an exception is warranted to permit the issuer to offer QHPs through the FFE.

[89 FR 8988, Feb. 8, 2024]

§ 156.225 Marketing and benefit design of QHPs.

A QHP issuer and its officials, employees, agents and representatives must—

(a) *State law applies.* Comply with any applicable State laws and regulations regarding marketing by health insurance issuers;

(b) *Non-discrimination.* Not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs; and

(c) *Plan marketing names.* Offer plans and plan variations with marketing names that include correct information, without omission of material fact, and do not include content that is misleading.

[77 FR 18469, Mar. 27, 2012, as amended at 88 FR 25922, Apr. 27, 2023]

§ 156.230 Network adequacy standards.

(a) *General requirement.* (1) Each QHP issuer must use a provider network and ensure that the provider network consisting of in-network providers, as available to all enrollees, meets the following standards:

(i) Includes essential community providers in accordance with §156.235;

(ii) Maintains a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to ensure that all services will be accessible without unreasonable delay; and

(iii) Is consistent with the rules for network plans of section 2702(c) of the PHS Act.

(2)(i) *Standards.* A QHP issuer on a Federally-facilitated Exchange must comply with the requirement in paragraph (a)(1)(ii) of this section by:

(A) For plan years beginning on or after January 1, 2023, meeting time and

distance standards established by the Federally-facilitated Exchange. Such time and distance standards will be developed for consistency with industry standards and published in guidance. Quantitative reviews of compliance with time and distance standards will be conducted using issuer-submitted data; and

(B) For plan years beginning on or after January 1, 2025, meeting appointment wait time standards established by the Federally-facilitated Exchange. Such appointment wait time standards will be developed for consistency with industry standards and published in guidance.

(ii) *Written justification.* If a plan applying for QHP certification to be offered through a Federally-facilitated Exchanges does not satisfy the network adequacy standards described in paragraphs (a)(2)(i)(A) and (B) of this section, the issuer must include it as part of its QHP application a justification describing how the plan's provider network provides an adequate level of service for enrollees and how the plan's provider network will be strengthened and brought closer to compliance with the network adequacy standards prior to the start of the plan year. The issuer must provide information as requested by the FFE to support this justification.

(3) The Federally-facilitated Exchange may grant an exception to the requirements in paragraphs (a)(2)(i)(A) and (B) of this section if the Exchange determines that making such health plan available through such Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates.

(4) A limited exception to the requirement described under paragraph (a)(1) of this section that each QHP issuer use a provider network is available to stand-alone dental plans issuers that sell plans in areas where it is prohibitively difficult for the issuer to establish a network of dental providers; this exception is not available to medical QHP issuers. Under this exception, an area is considered ''prohibitively difficult'' for the stand-alone dental plan issuer to establish a network of dental providers based on attestations from State departments of insurance in States with at least 80 percent of counties classified as Counties with Extreme Access Considerations (CEAC) that at least one of the following factors exists in the area of concern: a significant shortage of dental providers, a significant number of dental providers unwilling to contract with Exchange issuers, or significant geographic limitations impacting consumer access to dental providers.

(b) *Access to provider directory.* (1) A QHP issuer must make its provider directory for a QHP available to the Exchange for publication online in accordance with guidance from HHS and to potential enrollees in hard copy upon request. In the provider directory, a QHP issuer must identify providers that are not accepting new patients.

(2) For plan years beginning on or after January 1, 2016, a QHP issuer must publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, the provider's location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS and OPM. A provider directory is easily accessible when—

(i) The general public is able to view all of the current providers for a plan in the provider directory on the issuer's public Web site through a clearly identifiable link or tab and without creating or accessing an account or entering a policy number; and

(ii) If a health plan issuer maintains multiple provider networks, the general public is able to easily discern which providers participate in which plans and which provider networks.

(c) *Increasing consumer transparency.* A QHP issuer in a Federally-facilitated Exchange must make available the information described in paragraph (b) of this section on its Web site in an HHS specified format and also submit this information to HHS, in a format and manner and at times determined by HHS.

(d) *Provider transitions.* A QHP issuer in a Federally-facilitated Exchange must—

(1) Make a good faith effort to provide written notice of discontinuation

of a provider 30 days prior to the effective date of the change or otherwise as soon as practicable, to enrollees who are patients seen on a regular basis by the provider or who receive primary care from the provider whose contract is being discontinued, irrespective of whether the contract is being discontinued due to a termination for cause or without cause, or due to a non-renewal;

(2) In cases where a provider is terminated without cause, allow an enrollee in an active course of treatment to continue treatment until the treatment is complete or for 90 days, whichever is shorter, at in-network cost-sharing rates.

(i) For the purposes of paragraph (d)(2) of this section, active course of treatment means:

(A) An ongoing course of treatment for a life-threatening condition, defined as a disease or condition for which likelihood of death is probable unless the course of the disease or condition is interrupted;

(B) An ongoing course of treatment for a serious acute condition, defined as a disease or condition requiring complex ongoing care which the covered person is currently receiving, such as chemotherapy, radiation therapy, or post-operative visits;

(C) The second or third trimester of pregnancy, through the postpartum period; or

(D) An ongoing course of treatment for a health condition for which a treating physician or health care provider attests that discontinuing care by that physician or health care provider would worsen the condition or interfere with anticipated outcomes.

(ii) Any QHP issuer decision made for a request for continuity of care under paragraph (d)(2) of this section must be subject to the health benefit plan's internal and external grievance and appeal processes in accordance with applicable State or Federal law or regulations.

(e) *Out-of-network cost-sharing.* Beginning for the 2018 and later benefit years, for a network to be deemed adequate, each QHP must:

(1) Notwithstanding §156.130(c), count the cost sharing paid by an enrollee for an essential health benefit provided by an out-of-network ancillary provider in an in-network setting towards the enrollee's annual limitation on cost sharing; or

(2) Provide a written notice to the enrollee by the longer of when the issuer would typically respond to a prior authorization request timely submitted, or 48 hours before the provision of the benefit, that additional costs may be incurred for an essential health benefit provided by an out-of- network ancillary provider in an in-network setting, including balance billing charges, unless such costs are prohibited under State law, and that any additional charges may not count toward the in-network annual limitation on cost sharing.

(f) [Reserved]

[77 FR 18469, Mar. 27, 2012, as amended at 80 FR 10873, Feb. 27, 2015; 81 FR 12349, Mar. 8, 2016; 86 FR 6178, Jan. 19, 2021; 87 FR 27391, May 6, 2022; 88 FR 25922, Apr. 27, 2023]

§ 156.235 Essential community providers.

(a) *General ECP standard.* (1) A QHP issuer must include in its provider network a sufficient number and geographic distribution of essential community providers (ECPs), where available, to ensure reasonable and timely access to a broad range of such providers for low-income individuals or individuals residing in Health Professional Shortage Areas within the QHP's service area, in accordance with the Exchange's network adequacy standards.

(2) A plan applying for QHP certification to be offered through a Federally-facilitated Exchange has a sufficient number and geographic distribution of ECPs if it demonstrates in its QHP application that—

(i) The QHP issuer's provider network includes as participating providers at least a minimum percentage, as specified by HHS, of available ECPs in each plan's service area collectively across all ECP categories defined under paragraph (a)(2)(ii)(B) of this section, and at least a minimum percentage of available ECPs in each plan's service area within certain individual ECP categories, as specified by HHS. Multiple providers at a single location will count as a single ECP toward both the

available ECPs in the plan's service area and the issuer's satisfaction of the ECP participation standard. For plans that use tiered networks, to count toward the issuer's satisfaction of the ECP standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For plans with two network tiers (for example, participating providers and preferred providers), such as many preferred provider organizations (PPOs), where cost-sharing is lower for preferred providers, only preferred providers will be counted towards ECP standards; and

(ii) The issuer of the plan offers contracts to—

(A) All available Indian health care providers in the service area, applying the special terms and conditions required by Federal law and regulations as referenced in the recommended model QHP addendum for Indian health care providers developed by HHS; and

(B) At least one ECP in each of the eight (8) ECP categories in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type. The ECP categories are: Federally Qualified Health Centers, Ryan White Program Providers, Family Planning Providers, Indian Health Care Providers, Inpatient Hospitals, Mental Health Facilities, Substance Use Disorder Treatment Centers, and Other ECP Providers. The Other ECP Providers category includes the following types of providers: Rural Health Clinics, Black Lung Clinics, Hemophilia Treatment Centers, Sexually Transmitted Disease Clinics, Tuberculosis Clinics, and Rural Emergency Hospitals.

(3) If a plan applying for QHP certification to be offered through a Federally-facilitated Exchange does not satisfy the ECP standard described in paragraph (a)(2) of this section, the issuer must include as part of its QHP application a narrative justification describing how the plan's provider network provides an adequate level of service for low-income enrollees or individuals residing in Health Professional Shortage Areas within the plan's service area and how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year.

(4) Nothing in paragraphs (a)(1) through (3) of this section requires any QHP to provide coverage for any specific medical procedure.

(5) A plan that provides a majority of covered professional services through physicians employed by the issuer or through a single contracted medical group may instead comply with the alternate standard described in paragraph (b) of this section.

(b) *Alternate ECP standard.* (1) A plan described in paragraph (a)(5) of this section must have a sufficient number and geographic distribution of employed providers and hospital facilities, or providers of its contracted medical group and hospital facilities, to ensure reasonable and timely access for low-income individuals or individuals residing in Health Professional Shortage Areas within the plan's service area, in accordance with the Exchange's network adequacy standards.

(2) A plan described in paragraph (a)(5) of this section applying for QHP certification to be offered through a Federally-facilitated Exchange has a sufficient number and geographic distribution of employed or contracted providers if it demonstrates in its QHP application that—

(i) The number of its providers that are located in Health Professional Shortage Areas or five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the Federal poverty level satisfies a minimum percentage, specified by HHS, of available ECPs in each plan's service area collectively across all ECP categories defined under paragraph (a)(2)(ii)(B) of this section, and at least a minimum percentage of available ECPs in each plan's service area within certain individual ECP categories, as specified by HHS. Multiple providers at a single location will count as a single ECP toward both the available ECPs in the plan's service area and the issuer's satisfaction of the ECP participation standard. For plans that use tiered networks, to count toward the issuer's satisfaction of the ECP standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For plans with

two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only preferred providers would be counted towards ECP standards; and

(ii) The issuer's integrated delivery system provides all of the categories of services provided by entities in each of the ECP categories in each county in the plan's service area as outlined in the general ECP standard, or otherwise offers a contract to at least one ECP outside of the issuer's integrated delivery system per ECP category in each county in the plan's service area that can provide those services to low-income, medically underserved individuals.

(3) If a plan does not satisfy the alternate ECP standard described in paragraph (b)(2) of this section, the issuer must include as part of its QHP application a narrative justification describing how the plan's provider networks provide an adequate level of service for low-income enrollees or individuals residing in Health Professional Shortage Areas within the plan's service area and how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year.

(c) *Definition.* An essential community provider is a provider that serves predominantly low-income, medically underserved individuals, including a health care provider defined in section 340B(a)(4) of the PHS Act; or described in section 1927(c)(1)(D)(i)(IV) of the Act as set forth by section 221 of Pub. L. 111–8; or a State-owned family planning service site, or governmental family planning service site, or not-for-profit family planning service site that does not receive Federal funding under special programs, including under Title X of the PHS Act, or an Indian health care provider, unless any of the above providers has lost its status under either of these sections, 340(B) of the PHS Act or 1927 of the Act as a result of violating Federal law.

(d) *Payment rates.* Nothing in paragraph (a) of this section may be construed to require a QHP issuer to contract with an ECP if such provider refuses to accept the same rates and contract provisions included in contracts accepted by similarly situated providers.

(e) *Payment of Federally qualified health centers.* If an item or service covered by a QHP is provided by a Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Act) to an enrollee of a QHP, the QHP issuer must pay the Federally qualified health center for the item or service an amount that is not less than the amount of payment that would have been paid to the center under section 1902(bb) of the Act for such item or service. Nothing in this paragraph (e) precludes a QHP issuer and Federally-qualified health center from agreeing upon payment rates other than those that would have been paid to the center under section 1902(bb) of the Act, as long as that rate is at least equal to the generally applicable payment rate of the issuer described in paragraph (d) of this section.

[80 FR 10873, Feb. 27, 2015, as amended at 88 FR 25922, Apr. 27, 2023]

§ 156.245 Treatment of direct primary care medical homes.

A QHP issuer may provide coverage through a direct primary care medical home that meets criteria established by HHS, so long as the QHP meets all requirements that are otherwise applicable and the services covered by the direct primary care medical home are coordinated with the QHP issuer.

§ 156.250 Meaningful access to qualified health plan information.

A QHP issuer must provide all information that is critical for obtaining health insurance coverage or access to health care services through the QHP, including applications, forms, and notices, to qualified individuals, applicants, qualified employers, qualified employees, and enrollees in accordance with the standards described in § 155.205(c) of this subchapter. Information is deemed to be critical for obtaining health insurance coverage or access to health care services if the issuer is required by law or regulation to provide the document to a qualified individual, applicant, qualified employer, qualified employee, or enrollee.

[80 FR 10874, Feb. 27, 2015]

§ 156.255 Rating variations.

(a) *Rating areas.* A QHP issuer, including an issuer of a multi-State plan, may vary premiums by the geographic rating area established under section 2701(a)(2) of the PHS Act.

(b) *Same premium rates.* A QHP issuer must charge the same premium rate without regard to whether the plan is offered through an Exchange, or whether the plan is offered directly from the issuer or through an agent.

§ 156.260 Enrollment periods for qualified individuals.

(a) *Individual market requirement.* A QHP issuer must:

(1) Enroll a qualified individual during the initial and annual open enrollment periods described in §155.410(b) and (e) of this subchapter, and abide by the effective dates of coverage established by the Exchange in accordance with §155.410(c) and (f) of this subchapter; and

(2) Make available, at a minimum, special enrollment periods described in §155.420(d) of this subchapter, for QHPs and abide by the effective dates of coverage established by the Exchange in accordance with §155.420(b) of this subchapter.

(b) *Notification of effective date.* A QHP issuer must notify a qualified individual of his or her effective date of coverage.

§ 156.265 Enrollment process for qualified individuals.

(a) *General requirement.* A QHP issuer must process enrollment in accordance with this section.

(b) *Enrollment through the Exchange for the individual market.* (1) A QHP issuer must enroll a qualified individual only if the Exchange—

(i) Notifies the QHP issuer that the individual is a qualified individual; and

(ii) Transmits information to the QHP issuer as provided in §155.400(a) of this subchapter.

(2) If an applicant initiates enrollment directly with the QHP issuer for enrollment through the Exchange, the QHP issuer must either—

(i) Direct the individual to file an application with the Exchange in accordance with §155.310, or

(ii) Ensure the applicant's completion of an eligibility verification and enrollment application through the Exchange Internet Web site as described in §155.405, or ensure that the eligibility application information is submitted for an eligibility determination through the Exchange-approved Web service subject to meeting the requirements in paragraph (b)(3) through (5) of this section;

(3) When an Internet Web site of an issuer is used to complete the Exchange eligibility application outlined in this section, at a minimum, the Internet Web site must:

(i) Use exactly the same eligibility application language as appears in the FFE Single Streamlined Application required in §155.405 of this subchapter, unless HHS approves a deviation;

(ii) Ensure that all necessary information for the consumer's applicable eligibility circumstances are submitted through the Exchange-approved Web service;

(iii) Ensure that the process used for consumers to complete the eligibility application complies with all applicable Exchange standards, including §§155.230 and 155.260(b) of this subchapter; and

(iv) Differentially display all standardized options in accordance with the requirements under §155.205(b)(1) in a manner consistent with that adopted by HHS for display on the Federally-facilitated Exchange Web site, unless HHS approves a deviation.

(4) An issuer must obtain HHS approval that the requirements of this section have been met prior to completing an applicant's eligibility application through the issuer's Internet Web site.

(5) HHS or its designee may periodically monitor and audit an agent, broker, or issuer to assess its compliance with the applicable requirements of this section.

(c) *Acceptance of enrollment information.* A QHP issuer must accept enrollment information consistent with the privacy and security requirements established by the Exchange in accordance with §155.260 and in an electronic format that is consistent with §155.270.

(d) *Premium payment.* A QHP issuer must follow the premium payment

process established by the Exchange in accordance with §155.240 of this subchapter and the payment rules established in §155.400(e) of this subchapter.

(e) *Enrollment information package.* A QHP issuer must provide new enrollees an enrollment information package that is compliant with accessibility and readability standards established in §155.230(b).

(f) *Enrollment reconciliation.* A QHP issuer must reconcile enrollment files with the Exchange in a format specified by the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) and resolve assigned updates no less than once a month in accordance with §155.400(d) of this subchapter, using the most recent enrollment information that is available and that has been verified to the best of the issuer's knowledge or belief.

(g) *Timely updates to enrollment records.* A QHP issuer offering plans through an Exchange must, in a format specified by the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform), either:

(1) Verify to the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) that the information in the enrollment reconciliation file received from the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) accurately reflects its enrollment data for the applicable benefit year in its next enrollment reconciliation file submission to the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform), and update its internal enrollment records accordingly; or

(2) Describe to the Exchange (or for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) within one reconciliation cycle any discrepancy it identifies in the enrollment reconciliation files it received from the Exchange (or for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform).

[77 FR 18469, Mar. 27, 2012, as amended at 78 FR 76218, Dec. 17, 2013; 79 FR 30351, May 27, 2014; 80 FR 10874, Feb. 27, 2015; 81 FR 12350, Mar. 8, 2016; 81 FR 94181, Dec. 22, 2016; 85 FR 29261, May 14, 2020]

§156.270 Termination of coverage or enrollment for qualified individuals.

(a) *General requirement.* A QHP issuer may only terminate enrollment in a QHP through the Exchange as permitted by the Exchange in accordance with §155.430(b) of this subchapter. (See also §147.106 of this subchapter for termination of coverage.)

(b) *Termination of coverage or enrollment notice requirement.* If a QHP issuer terminates an enrollee's coverage or enrollment in a QHP through the Exchange in accordance with §155.430(b) of this subchapter, the QHP issuer must, promptly and without undue delay:

(1) Provide the enrollee with a notice of termination that includes the termination effective date and reason for termination.

(2) [Reserved]

(c) *Termination of coverage or enrollment due to non-payment of premium.* A QHP issuer must establish a standard policy for the termination of enrollment of enrollees through the Exchange due to non-payment of premium as permitted by the Exchange in §155.430(b)(2)(ii) of this subchapter. This policy for the termination of enrollment:

(1) Must include the grace period for enrollees receiving advance payments of the premium tax credits as described in paragraph (d) of this section; and

(2) Must be applied uniformly to enrollees in similar circumstances.

(d) *Grace period for recipients of advance payments of the premium tax credit.* A QHP issuer must provide a grace period of 3 consecutive months for an enrollee, who when failing to timely pay premiums, is receiving advance payments of the premium tax credit. During the grace period, the QHP issuer must:

(1) Pay all appropriate claims for services rendered to the enrollee during the first month of the grace period

and may pend claims for services rendered to the enrollee in the second and third months of the grace period;

(2) Notify HHS of such non-payment; and,

(3) Notify providers of the possibility for denied claims when an enrollee is in the second and third months of the grace period.

(e) *Advance payments of the premium tax credit.* For the 3-month grace period described in paragraph (d) of this section, a QHP issuer must:

(1) Continue to collect advance payments of the premium tax credit on behalf of the enrollee from the Department of the Treasury.

(2) Return advance payments of the premium tax credit paid on the behalf of such enrollee for the second and third months of the grace period if the enrollee exhausts the grace period as described in paragraph (g) of this section.

(f) *Notice of non-payment of premiums.* If an enrollee is delinquent on premium payment, the QHP issuer must provide the enrollee with notice of such payment delinquency. Issuers offering QHPs in Exchanges on the Federal platform must provide such notices promptly and without undue delay, within 10 business days of the date the issuer should have discovered the delinquency.

(g) *Exhaustion of grace period.* If an enrollee receiving advance payments of the premium tax credit exhausts the 3-month grace period in paragraph (d) of this section without paying all outstanding premiums, subject to a premium payment threshold implemented under §155.400(g) of this subchapter, if applicable, the QHP issuer must terminate the enrollee's enrollment through the Exchange on the effective date described in §155.430(d)(4) of this subchapter, provided that the QHP issuer meets the notice requirement specified in paragraph (b) of this section.

(h) *Records of termination of coverage.* QHP issuers must maintain records in accordance with Exchange standards established in accordance with §155.430(c) of this subchapter.

(i) *Effective date of termination of coverage or enrollment.* QHP issuers must abide by the termination of coverage or enrollment effective dates described in §155.430(d) of this subchapter.

(j) *Operational instructions.* QHP issuers must follow the transaction rules established by the Exchange in accordance with §155.430(e) of this subchapter.

[77 FR 18469, Mar. 27, 2012, as amended at 78 FR 42322, July 15, 2013; 78 FR 54143, Aug. 30, 2013; 79 FR 30351, May 27, 2014; 80 FR 10874, Feb. 27, 2015; 81 FR 12350, Mar. 8, 2016; 81 FR 53032, Aug. 11, 2016; 85 FR 29261, May 14, 2020; 88 FR 25923, Apr. 27, 2023]

§ 156.272 Issuer participation for the full plan year.

(a) An issuer offering a QHP through an individual market Exchange must make the QHP available for enrollment through the Exchange for the full plan year for which the plan was certified, including to eligible enrollees during limited open enrollment periods, unless a basis for suppression under §156.815 applies.

(b) Unless a basis for suppression under §156.815 applies, an issuer offering a QHP through a SHOP must make the QHP available for enrollment through the SHOP for the full plan year for which the QHP was certified.

(c) An issuer offering a QHP through a Federally-facilitated Exchange or a Federally-facilitated SHOP that does not comply with paragraph (a) or (b) of this section may, at the discretion of HHS, be precluded from offering QHPs in a Federally-facilitated Exchange or Federally-facilitated SHOP for up to the two succeeding plan years.

[81 FR 94181, Dec. 22, 2016]

§ 156.275 Accreditation of QHP issuers.

(a) *General requirement.* A QHP issuer must:

(1) Be accredited on the basis of local performance of its QHPs in the following categories by an accrediting entity recognized by HHS:

(i) Clinical quality measures, such as the Healthcare Effectiveness Data and Information Set;

(ii) Patient experience ratings on a standardized CAHPS survey;

(iii) Consumer access;

(iv) Utilization management;

(v) Quality assurance;

(vi) Provider credentialing;

(vii) Complaints and appeals;

(viii) Network adequacy and access; and

(ix) Patient information programs, and

(2) Authorize the accrediting entity that accredits the QHP issuer to release to the Exchange and HHS a copy of its most recent accreditation survey, together with any survey-related information that HHS may require, such as corrective action plans and summaries of findings.

(b) *Timeframe for accreditation.* A QHP issuer must be accredited within the timeframe established by the Exchange in accordance with §155.1045 of this subchapter. The QHP issuer must maintain accreditation so long as the QHP issuer offers QHPs.

(c) *Accreditation*—(1) *Recognition of accrediting entity by HHS*—(i) *Application.* An accrediting entity may apply to HHS for recognition. An application must include the documentation described in paragraph (c)(4) of this section and demonstrate, in a concise and organized fashion how the accrediting entity meets the requirements of paragraphs (c)(2) and (3) of this section.

(ii) *Proposed notice.* Within 60 days of receiving a complete application as described in paragraph (c)(1)(i) of this section, HHS will publish a notice in the FEDERAL REGISTER identifying the accrediting entity making the request, summarizing HHS's analysis of whether the accrediting entity meets the criteria described in paragraphs (c)(2) and (3) of this section, and providing no less than a 30-day public comment period about whether HHS should recognize the accrediting entity.

(iii) *Final notice.* After the close of the comment period described in paragraph (c)(1)(ii) of this section, HHS will notify the public in the FEDERAL REGISTER of the names of the accrediting entities recognized and those not recognized as accrediting entities by the Secretary of HHS to provide accreditation of QHPs.

(iv) *Other recognition.* Upon completion of conditions listed in paragraphs (c)(2), (3), and (4) of this section, HHS recognized, and provided notice to the public in the FEDERAL REGISTER, the National Committee for Quality Assurance (NCQA) and URAC as accrediting entities by the Secretary of HHS to provide accreditation of QHPs meeting the requirement of this section.

(2)(i) *Scope of accreditation.* Subject to paragraphs (c)(2)(ii), (iii), and (iv) of this section, recognized accrediting entities must provide accreditation within the categories identified in paragraphs (a)(1) of this section.

(ii) *Clinical quality measures.* Recognized accrediting entities must include a clinical quality measure set in their accreditation standards for health plans that:

(A) Spans a breadth of conditions and domains, including, but not limited to, preventive care, mental health and substance abuse disorders, chronic care, and acute care.

(B) Includes measures that are applicable to adults and measures that are applicable to children.

(C) Aligns with the priorities of the National Strategy for Quality Improvement in Health Care issued by the Secretary of HHS and submitted to Congress on March 12, 2011;

(D) Only includes measures that are either developed or adopted by a voluntary consensus standards setting body (such as those described in the National Technology and Transfer Advancement of Act of 1995 (NTTAA) and Office of Management and Budget (OMB) Circular A–119 (1998)) or, where appropriate endorsed measures are unavailable, are in common use for health plan quality measurement and meet health plan industry standards; and

(E) Is evidence-based.

(iii) *Level of accreditation.* Recognized accrediting entities must provide accreditation at the Exchange product type level unless the product type level of accreditation is not methodologically sound. In such cases, the recognized accrediting entity must demonstrate that the Exchange product type level accreditation is not methodologically sound as a condition of the Exchange granting an exception to authorize accreditation at an aggregated level.

(iv) *Network adequacy.* The network adequacy standards for accreditation used by the recognized accrediting entities must, at a minimum, be consistent with the general requirements

for network adequacy for QHP issuers codified in §156.230(a)(2) and (a)(3).

(3) *Methodological and scoring criteria for accreditation.* Recognized accrediting entities must use transparent and rigorous methodological and scoring criteria.

(4) *Documentation.* An accrediting entity applying to be recognized under the process described in (c)(1) of this section must provide the following documentation:

(i) To be recognized, an accrediting entity must provide current accreditation standards and requirements, processes and measure specifications for performance measures to demonstrate that it meets the conditions described in paragraphs (c)(2) and (3) of this section to HHS.

(ii) Recognized accrediting entities must provide to HHS any proposed changes or updates to the accreditation standards and requirements, processes, and measure specifications for performance measures with 60 days notice prior to public notification.

(5) *Data sharing requirements between the recognized accrediting entities and Exchanges.* When authorized by an accredited QHP issuer pursuant to paragraph (a)(2) of this section, recognized accrediting entities must provide the following QHP issuer's accreditation survey data elements to the Exchange, other than personally identifiable information (as described in OMB Memorandum M–07–16), in which the issuer plans to operate one or more QHPs during the annual certification period or as changes occur to these data throughout the coverage year—the name, address, Health Insurance Oversight System (HIOS) issuer identifier, and unique accreditation identifier(s) of the QHP issuer and its accredited product line(s) and type(s) which have been released; and for each accredited product type:

(i) HIOS product identifier (if applicable);

(ii) Accreditation status, survey type, or level (if applicable);

(iii) Accreditation score;

(iv) Expiration date of accreditation; and

(v) Clinical quality measure results and adult and child CAHPS measure survey results (and corresponding expiration dates of these data) at the level specified by the Exchange.

[77 FR 18469, Mar. 27, 2012, as amended at 77 FR 42671, July 20, 2012; 78 FR 12869, Feb. 25, 2013]

§ 156.280 Segregation of funds for abortion services.

(a) *State opt-out of abortion coverage.* A QHP issuer must comply with a State law that prohibits abortion coverage in QHPs.

(b) *Termination of opt out.* A QHP issuer may provide coverage of abortion services through the Exchange in a State described in paragraph (a) of this section if the State repeals such law.

(c) *Voluntary choice of coverage of abortion services.* Notwithstanding any other provision of title I of the Affordable Care Act (or any other amendment made under that title):

(1) Nothing in title I of the Affordable Care Act (or any amendments by that title) shall be construed to require a QHP issuer to provide coverage of services described in paragraph (d) of this section as part of its essential health benefits, as described in section 1302(b) of the Affordable Care Act, for any plan year.

(2) Subject to paragraphs (a) and (b) of this section, the QHP issuer must determine whether or not the QHP provides coverage of services described in paragraph (d) of this section as part of such benefits for the plan year.

(d) *Abortion services*—(1) *Abortions for which public funding is prohibited.* The services described in this paragraph are abortion services for which the expenditure of Federal funds appropriated for HHS is not permitted, based on the law in effect 6 months before the beginning of the plan year involved.

(2) *Abortions for which public funding is allowed.* The services described in this paragraph are abortion services for which the expenditure of Federal funds appropriated for HHS is permitted, based on the law in effect 6 months before the beginning of the plan year involved.

(e) *Prohibition on the use of Federal funds.* (1) If a QHP provides coverage of services described in paragraph (d)(1) of this section, the QHP issuer must not use any amount attributable to any of

the following for the purposes of paying for such services:

(i) The credit under section 36B of the Code and the amount (if any) of the advance payment of the credit under section 1412 of the Affordable Care Act;

(ii) Any cost-sharing reduction under section 1402 of the Affordable Care Act and the amount (if any) of the advance payments of the reduction under section 1412 of the Affordable Care Act.

(2) *Establishment of allocation accounts.* In the case of a QHP to which paragraph (e)(1) of this section applies, the QHP issuer must:

(i) Collect from each enrollee in the QHP (without regard to the enrollee's age, sex, or family status) a separate payment for each of the following:

(A) An amount equal to the portion of the premium to be paid directly by the enrollee for coverage under the QHP of services other than services described in (d)(1) of this section (after reductions for credits and cost-sharing reductions described in paragraph (e)(1) of this section); and

(B) An amount equal to the actuarial value of the coverage of services described in paragraph (d)(1) of this section.

(ii) An issuer will be considered to satisfy the obligation in paragraph (e)(2)(i) of this section if it sends the policy holder a single monthly invoice or bill that separately itemizes the premium amount for coverage of abortion services described in paragraph (d)(1) of this section; sends the policy holder a separate monthly bill for these services; or sends the policy holder a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services, and specifies the charge.

(iii) Deposit all such separate payments into separate allocation accounts as provided in paragraph (e)(3) of this section. In the case of an enrollee whose premium for coverage under the QHP is paid through employee payroll deposit, the separate payments required under paragraph (e)(2)(i) of this section shall each be paid by a separate deposit.

(3) *Segregation of funds.* (i) The QHP issuer to which paragraph (e)(1) of this section applies must establish allocation accounts described in paragraph (e)(3)(ii) of this section for enrollees receiving the amounts described in paragraph (e)(1) of this section.

(ii) *Allocation accounts.* The QHP issuer to which paragraph (e)(1) of this section applies must deposit:

(A) All payments described in paragraph (e)(2)(i)(A) of this section into a separate account that consists solely of such payments and that is used exclusively to pay for services other than the services described in paragraph (d)(1) of this section;

(B) All payments described in paragraph (e)(2)(i)(B) of this section into a separate account that consists solely of such payments and that is used exclusively to pay for services described in paragraph (d)(1) of this section.

(4) *Actuarial value.* The QHP issuer must estimate the basic per enrollee, per month cost, determined on an average actuarial basis, for including coverage under the QHP of services described in paragraph (d)(1) of this section. In making such an estimate, the QHP issuer:

(i) May take into account the impact on overall costs of the inclusion of such coverage, but may not take into account any cost reduction estimated to result from such services, including prenatal care, delivery, or postnatal care;

(ii) Must estimate such costs as if such coverage were included for the entire population covered; and

(iii) May not estimate such a cost at less than one dollar per enrollee, per month.

(5) *Ensuring compliance with segregation requirements.* (i) Subject to paragraph (e)(5)(iv) of this section, the QHP issuer must comply with the efforts or direction of the State health insurance commissioner to ensure compliance with this section through the segregation of QHP funds in accordance with applicable provisions of generally accepted accounting requirements, circulars on funds management of the Office of Management and Budget and guidance on accounting of the Government Accountability Office.

(ii) Each QHP issuer that participates in an Exchange and offers coverage for services described in paragraph (d)(1) of this section should, as a

condition of participating in an Exchange, submit a plan that details its process and methodology for meeting the requirements of section 1303(b)(2)(C), (D), and (E) (hereinafter, ''segregation plan'') to the State health insurance commissioner. The segregation plan should describe the QHP issuer's financial accounting systems, including appropriate accounting documentation and internal controls, that would ensure the segregation of funds required by section 1303(b)(2)(C), (D), and (E), and should include:

(A) The financial accounting systems, including accounting documentation and internal controls, that would ensure the appropriate segregation of payments received for coverage of services described in paragraph (d)(1) of this section from those received for coverage of all other services;

(B) The financial accounting systems, including accounting documentation and internal controls, that would ensure that all expenditures for services described in paragraph (d)(1) of this section are reimbursed from the appropriate account; and

(C) An explanation of how the QHP issuer's systems, accounting documentation, and controls meet the requirements for segregation accounts under the law.

(iii) Each QHP issuer participating in the Exchange must provide to the State insurance commissioner an annual assurance statement attesting that the plan has complied with section 1303 of the Affordable Care Act and applicable regulations.

(iv) Nothing in this clause shall prohibit the right of an individual or QHP issuer to appeal such action in courts of competent jurisdiction.

(f) *Rules relating to notice*—(1) *Notice.* A QHP that provides for coverage of services in paragraph (d)(1) of this section, must provide a notice to enrollees, only as part of the summary of benefits and coverage explanation, at the time of enrollment, of such coverage.

(2) *Rules relating to payments.* The notice described in paragraph (f)(1) of this section, any advertising used by the QHP issuer with respect to the QHP, any information provided by the Exchange, and any other information specified by HHS must provide information only with respect to the total amount of the combined payments for services described in paragraph (d)(1) of this section and other services covered by the QHP.

(g) *No discrimination on basis of provision of abortion.* No QHP offered through an Exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.

(h) *Application of State and Federal laws regarding abortions*—(1) *No preemption of State laws regarding abortion.* Nothing in the Affordable Care Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor.

(2) *No effect on Federal laws regarding abortion.* Nothing in the Affordable Care Act shall be construed to have any effect on Federal laws regarding:

(i) Conscience protection;

(ii) Willingness or refusal to provide abortion; and

(iii) Discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.

(3) *No effect on Federal civil rights law.* Nothing in section 1303(c) of the Affordable Care Act shall alter the rights and obligations of employees and employers under Title VII of the Civil Rights Act of 1964.

(i) *Application of emergency services laws.* Nothing in the Affordable Care Act shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law, including section 1867 of the Act (popularly known as ''EMTALA'').

[77 FR 18469, Mar. 27, 2012, as amended at 84 FR 71710, Dec. 27, 2019; 85 FR 2888, Jan. 17, 2020; 85 FR 27629, May 8, 2020; 86 FR 53506, Sept. 27, 2021]

§ 156.285 Additional standards specific to SHOP for plan years beginning prior to January 1, 2018.

(a) *SHOP rating and premium payment requirements.* QHP issuers offering a QHP through a SHOP must:

(1) Accept payment from the SHOP on behalf of a qualified employer or an enrollee in accordance with § 155.705(b)(4) of this subchapter;

(2) Adhere to the SHOP timeline for rate setting as established in § 155.705(b)(6) of this subchapter; and

(3) Charge the same contract rate for a plan year.

(4)(i) Adhere to the premium rating standards described in § 147.102 of this subchapter regardless of whether the QHP being sold through the SHOP is sold in the small group market or the large group market; and

(ii) Effective in plan years beginning on or after January 1, 2015, a QHP issuer in a Federally-facilitated SHOP may not offer to an employer premiums that are based on average enrollee premium amounts under § 147.102(c)(3) of this subchapter, if the employer elects to offer coverage to its employees under § 155.705(b)(3)(iv)(A) of this subchapter. This paragraph (a)(4)(ii) also applies to stand-alone dental plans in a Federally-facilitated SHOP, if the employer elects to offer coverage to its employees under § 155.705(b)(3)(v)(B) of this subchapter.

(b) *Enrollment periods for the SHOP.* QHP issuers offering a QHP through the SHOP must:

(1) Enroll a qualified employee in accordance with the qualified employer's initial and annual employee open enrollment periods described in § 155.725 of this subchapter;

(2) Provide special enrollment periods as described in § 155.725(j);

(3) Provide an enrollment period for an employee who becomes a qualified employee outside of the initial or annual open enrollment period as described in § 155.725(g) of this subchapter; and

(4) Adhere to effective dates of coverage established in accordance with § 155.725 of this subchapter.

(c) *Enrollment process for the SHOP.* A QHP issuer offering a QHP through the SHOP must:

(1) Adhere to the enrollment timeline and process for the SHOP as described in § 155.720(b) of this subchapter;

(2) Receive enrollment information in an electronic format, in accordance with the requirements in §§ 155.260 and 155.270 of this subchapter, from the SHOP as described in § 155.720(c);

(3) Notify new enrollees of their effective date of coverage consistent with § 155.720(e) of this subchapter.

(4) Provide new enrollees with the enrollment information package as described in § 156.265(e);

(5) Send enrollment reconciliation files on at least a monthly basis, and, in a Federally-facilitated SHOP, according to a process, timeline, and file format established by the Federally-facilitated SHOP;

(6) Acknowledge receipt of enrollment information in accordance with SHOP standards; and

(7) Enroll all qualified employees consistent with the plan year of the applicable qualified employer.

(8) A QHP issuer must enroll a qualified employee only if the SHOP—

(i) Notifies the QHP issuer that the employee is a qualified employee;

(ii) Transmits information to the QHP issuer as provided in § 155.400(a) of this subchapter; and

(iii) Effective for QHPs offered through a Federally-facilitated SHOP in plan years beginning on or after January 1, 2015, does not send a cancellation notice to the QHP issuer prior to the effective date of coverage.

(d) *Termination of coverage or enrollment in the SHOP.* QHP issuers offering a QHP through the SHOP must:

(1) Comply with the following requirements with respect to termination of enrollees in the SHOP:

(i)(A) Effective in plan years beginning on or after January 1, 2015, requirements regarding termination of coverage or enrollment established in § 155.735 of this subchapter, if applicable to the coverage or enrollment being terminated; otherwise

(B) General requirements regarding termination of coverage or enrollment established in § 156.270(a).

(ii) If a QHP issuer terminates an enrollee's coverage or enrollment through the SHOP in accordance with

§155.735(d)(1)(iii) or (v) of this subchapter, the QHP issuer must notify the qualified employer and the enrollee of the termination. Such notice must include the termination effective date and reason for termination, and must be sent within 3 business days if an electronic notice is sent, and within 5 business days if a mailed hard copy notice is sent. When a primary subscriber and his or her dependents live at the same address, a separate termination notice need not be sent to each dependent at that address, provided that the notice sent to each primary subscriber at that address contains all required information about the termination for the primary subscriber and his or her dependents at that address.

(iii)(A) Effective in plan years beginning on or after January 1, 2015, requirements regarding termination of coverage or enrollment effective dates as set forth in §155.735 of this subchapter, if applicable to the coverage or enrollment being terminated; otherwise

(B) Requirements regarding termination of coverage or enrollment effective dates as set forth in §156.270(i).

(2) [Reserved]

(e) *Participation rules.* QHP issuers offering a QHP through the SHOP may impose group participation rules for the offering of health insurance coverage in connection with a QHP only if and to the extent authorized by the SHOP in accordance with §155.705 of this subchapter.

(f) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Additional standards specific to SHOP for plan years beginning on or after January 1, 2018 are in §156.286.

[77 FR 18469, Mar. 27, 2012, as amended at 78 FR 15535, Mar. 11, 2013; 78 FR 33240, June 4, 2013; 78 FR 54143, Aug. 30, 2013; 79 FR 13840, Mar. 11, 2014; 80 FR 10874, Feb. 27, 2015; 80 FR 10875, Feb. 27, 2015; 81 FR 12350, Mar. 8, 2016; 83 FR 17069, Apr. 17, 2018]

§156.286 Additional standards specific to SHOP for plan years beginning on or after January 1, 2018.

(a) *SHOP rating and premium payment requirements.* QHP issuers offering a QHP through a SHOP must:

(1) Accept payment from a qualified employer or an enrollee, or a SHOP on behalf of a qualified employer or enrollee, in accordance with applicable SHOP requirements.

(2) Adhere to the SHOP timeline for rate setting as established in §155.706(b)(6) of this subchapter;

(3) Charge the same contract rate for a plan year; and

(4) Adhere to the premium rating standards described in §147.102 of this subchapter regardless of whether the QHP being sold through the SHOP is sold in the small group market or the large group market.

(b) *Enrollment periods and processes for the SHOP.* QHP issuers offering a QHP through the SHOP must adhere to enrollment periods and processes established by the SHOP, consistent with §155.726 of this subchapter, and establish a uniform enrollment timeline and process for enrolling qualified employers and employer group members.

(c) *Enrollment process for the SHOP.* A QHP issuer offering a QHP through the SHOP must:

(1) Provide new enrollees with the enrollment information package as described in §156.265(e); and

(2) Enroll all qualified employees consistent with the plan year of the applicable qualified employer.

(d) *Participation rules.* QHP issuers offering a QHP through the SHOP may impose group participation rules for the offering of health insurance coverage in connection with a QHP only if and to the extent authorized by the SHOP in accordance with §155.706 of this subchapter.

(e) *Employer choice.* QHP issuers offering a QHP through the SHOP must accept enrollments from groups in accordance with the employer choice policies applicable to the SHOP under §155.706(b)(3) of this subchapter.

(f) *Identification of SHOP enrollments.* QHP issuers offering a QHP through the SHOP must use a uniform enrollment form, maintain processes sufficient to identify whether a group market enrollment is an enrollment through the SHOP, and maintain records of SHOP enrollments for a period of 10 years following the enrollment.

(g) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

[83 FR 17069, Apr. 17, 2018]

§ 156.290 Non-certification and decertification of QHPs.

(a) *Non-certification for a subsequent, consecutive certification cycle.* If a QHP issuer elects not to seek certification for a subsequent, consecutive certification cycle with the Exchange, the QHP issuer, at a minimum, must—

(1) Notify the Exchange of its decision prior to the beginning of the recertification process and adhere to the procedures adopted by the Exchange in accordance with §155.1075 of this subchapter;

(2) Fulfill its obligation to cover benefits for each enrollee through the end of the plan or benefit year through the Exchange;

(3) Fulfill data reporting obligations from the last plan or benefit year of the certification;

(4) Provide notice to enrollees as described in paragraph (b) of this section; and

(5) Terminate the coverage or enrollment through the Exchange of enrollees in the QHP in accordance with §156.270, as applicable.

(b) *Notice of QHP non-availability.* When, for a subsequent, consecutive certification cycle, a QHP issuer elects not to seek certification with the Exchange, or the Exchange denies certification of a QHP, the QHP issuer must provide written notice to each enrollee in the form and manner specified by the Secretary under §147.106 of this subchapter.

(c) *Decertification.* If a QHP is decertified by the Exchange, the QHP issuer must terminate the enrollment of enrollees through the Exchange only after:

(1) The Exchange has made notification as described in §155.1080 of this subchapter; and

(2) Enrollees have an opportunity to enroll in other coverage.

[77 FR 18469, Mar. 27, 2012, as amended at 80 FR 10875, Feb. 27, 2015; 81 FR 94181, Dec. 22, 2016]

§ 156.295 Prescription drug distribution and cost reporting by QHP issuers.

(a) *General requirement.* In a form, manner, and at such times specified by HHS, a QHP issuer that administers a prescription drug benefit without the use of a pharmacy benefit manager must provide to HHS the following information:

(1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed;

(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding bona fide service fees) that the QHP issuer negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.

(i) Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

(ii) [Reserved]

(b) *Limitation on disclosure.* Information disclosed by a QHP issuer under this section shall not be disclosed by HHS, except that HHS may disclose the information in a form which does not disclose the identity of a specific QHP or prices charged for specific drugs, for the following purposes:

(1) As HHS determines to be necessary to carry out section 1150A or part D of title XVIII of the Act;

(2) To permit the Comptroller General to review the information provided;

(3) To permit the Director of the Congressional Budget Office to review the information provided; or

(4) To States to carry out section 1311 of the Affordable Care Act.

(c) *Penalties.* A QHP issuer that fails to report the information described in paragraph (a) of this section to HHS on a timely basis or knowingly provides false information will be subject to the provisions of subsection (b)(3)(C) of section 1927 of the Act.

[77 FR 18469, Mar. 27, 2012, as amended at 86 FR 24292, May 5, 2021]

Subpart D—Standards for Qualified Health Plan Issuers for Specific Types of Exchanges

SOURCE: 78 FR 54143, Aug. 30, 2013, unless otherwise noted.

§ 156.330 Changes of ownership of issuers of Qualified Health Plans in Federally-facilitated Exchanges.

When a QHP issuer that offers one or more QHPs in a Federally-facilitated Exchange undergoes a change of ownership as recognized by the State in which the issuer offers the QHP, the QHP issuer must notify HHS of the change in a manner to be specified by HHS, and provide the legal name and Taxpayer Identification Number (TIN) of the new owner and the effective date of the change at least 30 days prior to the effective date of the change of ownership. The new owner must agree to adhere to all applicable statutes and regulations.

[78 FR 65096, Oct. 30, 2013]

§ 156.340 Standards for downstream and delegated entities.

(a) *General requirement.* Effective October 1, 2013, notwithstanding any relationship(s) that a QHP issuer may have with delegated and downstream entities, a QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities with all applicable Federal standards related to Exchanges. The applicable standards depend on the Exchange model type in which the QHP is offered, as described in paragraphs (a)(1) and (2) of this section.

(1) QHP issuers participating in Exchange models that do not use the Federal platform, including State Exchanges and State Exchange SHOPs. QHP issuers maintain responsibility for ensuring their downstream and delegated entities comply with the Federal standards related to Exchanges, including the standards in subpart C of this part with respect to each of its QHPs on an ongoing basis, as well as the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 and, in the small group market, §§ 155.705 and 155.706 of this subchapter, unless the standard is specifically applicable to a Federally-facilitated Exchange or FF–SHOP;

(2) QHP issuers participating in Exchanges that use the Federal platform, including Federally-facilitated Exchanges, FF–SHOPs, SBE–FPs, and SBE–FP–SHOPs. QHP issuers maintain responsibility for ensuring their downstream and delegated entities comply with Federal standards related to Exchanges, including the standards in subpart C of part 156 with respect to each of its QHPs on an ongoing basis, as well as the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 of this subchapter and, in the small group market, §§ 155.705 and 155.706 of this subchapter if applicable to the Exchange type in which the QHP issuer is operating. QHP issuers are also responsible for their downstream and delegated entities' compliance with the standards of § 155.220 of this subchapter with respect to assisting with enrollment in QHPs, and the standards of §§ 156.705 and 156.715 of this subchapter for maintenance of records and compliance reviews if applicable to the Exchange type in which the QHP issuer is operating.

(b) *Delegation agreement specifications.* If any of the QHP issuer's activities or obligations, in accordance with paragraph (a) of this section, are delegated to other parties, the QHP issuer's agreement with any delegated or downstream entity must—

(1) Specify the delegated activities and reporting responsibilities;

(2) Provide for revocation of the delegated activities and reporting standards or specify other remedies in instances where HHS or the QHP issuer determines that such parties have not performed satisfactorily;

(3) Specify that the delegated or downstream entity must comply with all applicable laws and regulations relating to the standards specified under paragraph (a) of this section;

(4) Specify that the delegated or downstream entity must permit access by the Secretary and the OIG or their designees in connection with their right to evaluate through an audit, inspection, or other means, to the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period;

(5) All agreements between issuers offering QHPs through an Exchange and delegated or downstream entities the issuers engage to support the issuer's activities on an Exchange must include language stating that the relevant Exchange authority may demand and receive the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period.

[78 FR 54143, Aug. 30, 2013, as amended at 87 FR 27392, May 6, 2022]

§ 156.350 Eligibility and enrollment standards for Qualified Health Plan issuers on State-based Exchanges on the Federal platform.

(a) In order to participate in a State-based Exchange on the Federal platform, a QHP issuer must comply with HHS regulations, and guidance pertaining to issuer eligibility and enrollment functions as if the issuer were an issuer of a QHP on a Federally-facilitated Exchange. These requirements include—

(1) Section 156.285(a)(4)(ii) regarding the premiums for plans offered on the SHOP, for plan years beginning prior to January 1, 2018;

(2) Section 156.285(c)(5) and (c)(8)(iii) regarding the enrollment process for SHOP, for plan years beginning prior to January 1, 2018; and

(3) Section 156.715 regarding compliance reviews of QHP issuers, to the extent relating directly to applicable eligibility and enrollment functions.

(4) Section 156.265(d) of this subchapter regarding binder payments and premium payment deadlines.

(b) HHS will permit issuers of QHPs in each State-based Exchange on the Federal platform to directly enroll applicants in a manner that is considered to be through the Exchange, as if the issuers were issuers of QHPs on Federally-facilitated Exchanges under § 156.1230(a), to the extent permitted by applicable State law.

(c) If the State-based Exchange on the Federal platform does not substantially enforce a requirement in paragraph (a) of this section against the issuer or plan, then HHS may do so, in accordance with the enforcement remedies in subpart I of this part, subject to the administrative review process in subpart J of this part.

[81 FR 12351, Mar. 8, 2016, as amended at 81 FR 94181, Dec. 22, 2016; 83 FR 17069, Apr. 17, 2018]

Subpart E—Health Insurance Issuer Responsibilities With Respect to Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

SOURCE: 78 FR 15535, Mar. 11, 2013, unless otherwise noted.

§ 156.400 Definitions.

The following definitions apply to this subpart:

Advance payments of the premium tax credit has the meaning given to the term in § 155.20 of this subchapter.

Affordable Care Act has the meaning given to the term in § 155.20 of this subchapter.

Annual limitation on cost sharing means the annual dollar limit on cost sharing required to be paid by an enrollee that is established by a particular qualified health plan.

De minimis variation means the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of

the health plan as established in §156.140(c).

De minimis variation for a silver plan variation means a −0 percentage point and +1 percentage point allowable AV variation.

Federal poverty level or *FPL* has the meaning given to the term in §155.300(a) of this subchapter.

Indian has the meaning given to the term in §155.300(a) of this subchapter.

Limited cost sharing plan variation means, with respect to a QHP at any level of coverage, the variation of such QHP described in §156.420(b)(2).

Maximum annual limitation on cost sharing means the highest annual dollar amount that qualified health plans (other than QHPs with cost-sharing reductions) may require in cost sharing for a particular year, as established for that year under §156.130.

Most generous or *more generous* means, as between a QHP (including a standard silver plan) or plan variation and one or more other plan variations of the same QHP, the standard plan or plan variation designed for the category of individuals last listed in §155.305(g)(3) of this subchapter. *Least generous* or *less generous* has the opposite meaning.

Plan variation means a zero cost sharing plan variation, a limited cost sharing plan variation, or a silver plan variation.

Reduced maximum annual limitation on cost sharing means the dollar value of the maximum annual limitation on cost sharing for a silver plan variation that remains after applying the reduction, if any, in the maximum annual limitation on cost sharing required by section 1402 of the Affordable Care Act as announced in the annual HHS notice of benefit and payment parameters.

Silver plan variation means, with respect to a standard silver plan, any of the variations of that standard silver plan described in §156.420(a).

Stand-alone dental plan means a plan offered through an Exchange under §155.1065 of this subchapter.

Standard plan means a QHP offered at one of the four levels of coverage, defined at §156.140, with an annual limitation on cost sharing that conforms to the requirements of §156.130(a). A standard plan at the bronze, silver, gold, or platinum level of coverage is referred to as a standard bronze plan, a standard silver plan, a standard gold plan, and a standard platinum plan, respectively.

Zero cost sharing plan variation means, with respect to a QHP at any level of coverage, the variation of such QHP described in §156.420(b)(1).

[78 FR 15535, Mar. 11, 2013, as amended at 78 FR 65097, Oct. 30, 2013; 87 FR 27392, May 6, 2022]

§156.410 Cost-sharing reductions for enrollees.

(a) *General requirement.* A QHP issuer must ensure that an individual eligible for cost-sharing reductions, as demonstrated by assignment to a particular plan variation, pays only the cost sharing required of an eligible individual for the applicable covered service under the plan variation. The cost-sharing reduction for which an individual is eligible must be applied when the cost sharing is collected.

(b) *Assignment to applicable plan variation.* If an individual is determined to be eligible to enroll in a QHP in the individual market offered through an Exchange and elects to do so, the QHP issuer must assign the individual under enrollment and eligibility information submitted by the Exchange as follows—

(1) If the individual is determined eligible by the Exchange for cost-sharing reductions under §155.305(g)(2)(i), (ii), or (iii) of this subchapter (subject to the special rule for family policies set forth in §155.305(g)(3) of this subchapter) and chooses to enroll in a silver health plan, the QHP issuer must assign the individual to the silver plan variation of the selected silver health plan described in §156.420(a)(1), (2), or (3), respectively.

(2) If the individual is determined eligible by the Exchange for cost-sharing reductions for Indians with lower household income under §155.350(a) of this subchapter (subject to the special rule for family policies set forth in §155.305(g)(3) of this subchapter), and chooses to enroll in a QHP, the QHP issuer must assign the individual to the zero cost sharing plan variation of the selected QHP with all cost sharing eliminated described in §156.420(b)(1).

(3) If the individual is determined by the Exchange to be eligible for cost-sharing reductions for Indians regardless of household income under §155.350(b) of this subchapter (subject to the special rule for family policies set forth in §155.305(g)(3) of this subchapter), and chooses to enroll in a QHP, the QHP issuer must assign the individual to the limited cost sharing plan variation of the selected QHP with the prohibition on cost sharing for benefits received from the Indian Health Service and certain other providers described in §156.420(b)(2).

(4) If the individual is determined by the Exchange not to be eligible for cost-sharing reductions (including eligibility under the special rule for family policies set forth in §155.305(g)(3) of this subchapter), and chooses to enroll in a QHP, the QHP issuer must assign the individual to the selected QHP with no cost-sharing reductions.

(c) *Improper cost-sharing reductions.* (1) If a QHP issuer fails to ensure that an individual assigned to a plan variation receives the cost-sharing reductions required under the applicable plan variation, taking into account §156.425(b) concerning continuity of deductibles and out-of-pocket amounts (if applicable), then the QHP issuer must notify the enrollee of the improper application of any cost-sharing reduction within 45 calendar days of discovery of such improper application, and refund any resulting excess cost sharing paid by or for the enrollee as follows:

(i) If the excess cost sharing was paid by the provider, the QHP issuer must refund the excess cost sharing to the provider within 45 calendar days of discovery of the improper application.

(ii) If the excess cost sharing was not paid by the provider and is not requested by the enrollee as a refund, the QHP issuer must, within 45 calendar days of discovery of the error, apply the excess cost sharing paid by or for the enrollee to the enrollee's portion of the premium (or refund the amount directly). If any excess premium remains, the QHP issuer must apply the excess premium to the enrollee's portion of the premium for each subsequent month for the remainder of the period of enrollment or benefit year until the excess is fully applied (or refund any remaining amount directly). If any excess premium remains at the end of the period of enrollment or benefit year, the QHP issuer must refund the enrollee any remaining excess cost sharing paid by or for the enrollee within 45 calendar days of the end of the period of enrollment or benefit year, whichever comes first.

(iii) If the excess cost sharing was not paid by the provider, and if a refund is requested by the enrollee, the refund must be provided to the enrollee within 45 calendar days of the date of the request.

(2) If a QHP issuer provides an individual assigned to a plan variation greater cost-sharing reductions than required under the applicable plan variation, taking into account §156.425(b) concerning continuity of deductibles and out-of-pocket amounts (if applicable), then the QHP issuer will not be eligible for reimbursement of any excess cost-sharing reductions provided to the enrollee, and may not seek reimbursement from the enrollee or the applicable provider for any of the excess cost-sharing reductions.

(d) *Improper assignment.* If a QHP issuer does not assign an individual to the applicable plan variation (or standard plan without cost-sharing reductions) in accordance with §§156.410(b) and 156.425(a) based on the eligibility and enrollment information or notification provided by the Exchange, then the QHP issuer must reassign the enrollee to the applicable plan variation (or standard plan without cost-sharing reductions) and notify the enrollee of the improper assignment such that:

(1) If the QHP issuer discovers the improper assignment between the first and fifteenth day of the month, the QHP issuer must reassign the enrollee to the correct plan variation (or standard plan without cost-sharing reductions) by the first day of the following month.

(2) If the QHP issuer discovers the improper assignment between the sixteen and the last day of the month, the QHP issuer must reassign the individual to the correct plan variation (or standard plan without cost-sharing reductions) by the first day of the second following month.

(3) If, pursuant to a reassignment under this paragraph (d), a QHP issuer reassigns an enrollee from a more generous plan variation to a less generous plan variation of a QHP (or a standard plan without cost-sharing reductions), the QHP issuer will not be eligible for reimbursement for any of the excess cost-sharing reductions provided to the enrollee following the effective date of eligibility required by the Exchange, and may not seek reimbursement from the enrollee or the applicable provider for any of the excess cost-sharing reductions.

(4) If, pursuant to a reassignment under this paragraph (d), a QHP issuer reassigns an enrollee from a less generous plan variation (or a standard plan without cost-sharing reductions) to a more generous plan variation of a QHP, the QHP issuer must recalculate the enrollee's liability for cost sharing paid between the effective date of eligibility required by the Exchange and the date on which the issuer effectuated the change, and must refund any excess cost sharing paid by or for the enrollee during such period as follows:

(i) If the excess cost sharing was paid by the provider, the QHP issuer must refund the excess cost sharing to the provider within 45 calendar days of discovery of the improper assignment.

(ii) If the excess cost sharing was not paid by the provider and is not requested by the enrollee as a refund, the QHP issuer must, within 45 calendar days of discovery of the improper assignment, apply the excess cost sharing paid by or for the enrollee to the enrollee's portion of the premium (or refund the amount directly). If any excess premium remains, the QHP issuer must apply the excess premium to the enrollee's portion of the premium for each subsequent month for the remainder of the period of enrollment or benefit year until the excess is fully applied (or refund the remaining amount directly). If any excess premium remains at the end of the period of enrollment or benefit year, the QHP issuer must refund the enrollee any remaining excess cost sharing paid by or for the enrollee within 45 calendar days of the end of the period of enrollment or benefit year, whichever comes first.

(iii) If the excess cost sharing was not paid by the provider, then, if the enrollee requests a refund, the refund must be provided to the enrollee within 45 calendar days of the date of the request.

[78 FR 15535, Mar. 11, 2013, as amended at 78 FR 65097, Oct. 30, 2013; 80 FR 10875, Feb. 27, 2015]

§ 156.420 Plan variations.

(a) *Submission of silver plan variations.* For each of its silver health plans that an issuer offers, or intends to offer in the individual market on an Exchange, the issuer must submit annually to the Exchange for certification prior to each benefit year the standard silver plan and three variations of the standard silver plan, as follows—

(1) For individuals eligible for cost-sharing reductions under §155.305(g)(2)(i) of this subchapter, a variation of the standard silver plan with:

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

(ii) Other cost-sharing reductions such that the AV of the silver plan variation is 94 percent plus or minus the de minimis variation for a silver plan variation;

(2) For individuals eligible for cost-sharing reductions under §155.305(g)(2)(ii) of this subchapter, a variation of the standard silver plan with:

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

(ii) Other cost-sharing reductions such that the AV of the silver plan variation is 87 percent plus or minus the de minimis variation for a silver plan variation; and

(3) For individuals eligible for cost-sharing reductions under §155.305(g)(2)(iii) of this subchapter, a variation of the standard silver plan with:

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

(ii) Other cost-sharing reductions such that the AV of the silver plan variation is 73 percent plus or minus the de minimis variation for a silver plan variation (subject to §156.420(h)).

(b) *Submission of zero and limited cost sharing plan variations.* For each of its health plans at any level of coverage that an issuer offers, or intends to offer in the individual market on an Exchange, the issuer must submit to the Exchange for certification the health plan and two variations of the health plan, as follows—

(1) For individuals eligible for cost-sharing reductions under §155.350(a) of this subchapter, a variation of the health plan with all cost sharing eliminated; and

(2) For individuals eligible for cost-sharing reductions under §155.350(b) of this subchapter, a variation of the health plan with no cost sharing on any item or service that is an EHB furnished directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization (each as defined in 25 U.S.C. 1603), or through referral under contract health services.

(c) *Benefit and network equivalence in silver plan variations.* A standard silver plan and each silver plan variation thereof must cover the same benefits and providers. Each silver plan variation is subject to all requirements applicable to the standard silver plan (except for the requirement that the plan have an AV as set forth in §156.140(b)(2)).

(d) *Benefit and network equivalence in zero and limited cost sharing plan variations.* A QHP and each zero cost sharing plan variation or limited cost sharing plan variation thereof must cover the same benefits and providers. The out-of-pocket spending required of enrollees in the zero cost sharing plan variation of a QHP for a benefit that is not an essential health benefit from a provider (including a provider outside the plan's network) may not exceed the corresponding out-of-pocket spending required in the limited cost sharing plan variation of the QHP and the corresponding out-of-pocket spending required in the silver plan variation of the QHP for individuals eligible for cost-sharing reductions under §155.305(g)(2)(i) of this subchapter, in the case of a silver QHP. The out-of-pocket spending required of enrollees in the limited cost sharing plan variation of the QHP for a benefit that is not an essential health benefit from a provider (including a provider outside the plan's network) may not exceed the corresponding out-of-pocket spending required in the QHP with no cost-sharing reductions. A limited cost sharing plan variation must have the same cost sharing for essential health benefits not described in paragraph (b)(2) of this section as the QHP with no cost-sharing reductions. Each zero cost sharing plan variation or limited cost sharing plan variation is subject to all requirements applicable to the QHP (except for the requirement that the plan have an AV as set forth in §156.140(b)).

(e) *Decreasing cost sharing and out-of-pocket spending in higher AV silver plan variations.* The cost sharing or out-of-pocket spending required of enrollees under any silver plan variation of a standard silver plan for a benefit from a provider (including a provider outside the plan's network) may not exceed the corresponding cost sharing or out-of-pocket spending required in the standard silver plan or any other silver plan variation thereof with a lower AV.

(f) *Minimum AV differential between 70 percent and 73 percent silver plan variations.* Notwithstanding any permitted de minimis variation in AV for a health plan or permitted de minimis variation for a silver plan variation, the AVs of a standard silver plan and the silver plan variation thereof described in paragraph (a)(3) of this section must differ by at least 2 percentage points.

(g) *Multi-state plans.* The U.S. Office of Personnel Management will determine the time and manner for multi-State plans, as defined in §155.1000(a) of this subchapter, to submit silver plan variations, zero cost sharing plan variations, and limited cost sharing plan variations.

(h) *Notice.* No later than November 1, 2015, for each plan variation that an issuer offers in accordance with the rules of this section, an issuer must provide a summary of benefits and coverage that accurately represents each plan variation consistent with the requirements set forth in §147.200 of this subchapter.

[78 FR 15535, Mar. 11, 2013, as amended at 79 FR 13840, Mar. 11, 2014; 80 FR 10875, Feb. 27, 2015; 86 FR 24292, May 5, 2021]

§156.425 Changes in eligibility for cost-sharing reductions.

(a) *Effective date of change in assignment.* If the Exchange notifies a QHP issuer of a change in an enrollee's eligibility for cost-sharing reductions (including a change in the individual's eligibility under the special rule for family policies set forth in §155.305(g)(3) of this subchapter due to a change in eligibility of another individual on the same policy), then the QHP issuer must change the individual's assignment such that the individual is assigned to the applicable standard plan or plan variation of the QHP as required under §156.410(b) as of the effective date of eligibility required by the Exchange.

(b) *Continuity of deductible and out-of-pocket amounts.* In the case of a change in assignment to a different plan variation (or standard plan without cost-sharing reductions) of the same QHP in the course of a benefit year under this section, the QHP issuer must ensure that any cost sharing paid by the applicable individual under previous plan variations (or standard plan without cost-sharing reductions) for that benefit year is taken into account in the new plan variation (or standard plan without cost-sharing reductions) for purposes of calculating cost sharing based on aggregate spending by the individual, such as for deductibles or for the annual limitations on cost sharing.

(c) *Notice upon assignment.* Beginning on January 1, 2016, if an individual's assignment to a standard plan or plan variation of the QHP changes in accordance with paragraph (a) of this section, the issuer must provide to that individual a summary of benefits and coverage that accurately reflects the new plan variation (or standard plan variation without cost-sharing reductions) in a manner consistent with §147.200 of this subchapter as soon as practicable following receipt of notice from the Exchange, but not later than 7 business days following receipt of notice.

[78 FR 15535, Mar. 11, 2013, as amended at 80 FR 10875, Feb. 27, 2015]

§156.430 Payment for cost-sharing reductions.

(a) [Reserved]

(b) *Advance payments for cost-sharing reductions.* (1) When there is an appropriation to make cost-sharing reduction payments to QHP issuers, a QHP issuer will receive periodic advance payments from HHS to the extent permitted by the appropriation and calculated in accordance with §155.1030(b)(3) of this subchapter.

(2) HHS may adjust the advance payment amount for a particular QHP during the benefit year if the QHP issuer provides evidence, certified by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies, that the advance payments for a particular QHP are likely to be substantially different than the cost-sharing reduction amounts that the QHP provides that will be reimbursed by HHS.

(c) *Submission of actual amounts*—(1) *General.* For each plan variation that a QHP issuer offers on the Exchange, it must submit to HHS, in the manner and timeframe established by HHS, for each policy, the total allowed costs for essential health benefits charged for the policy for the benefit year, broken down by all of the following:

(i) The amount the issuer paid.

(ii) The amount the enrollee(s) paid.

(iii) The amount the enrollee(s) would have paid under the standard plan without cost-sharing reductions.

(2) *Standard methodology.* A QHP issuer must calculate the value of the amount the enrollee(s) would have paid under the standard plan without cost-sharing reductions by applying the actual cost-sharing requirements for the standard plan to the allowed costs for essential health benefits under the enrollee's policy for the benefit year.

(i) For reconciliation of cost-sharing reduction amounts advanced for the

2014 and 2015 benefit years, an issuer of a QHP using the standard or simplified methodology may calculate claims amounts attributable to EHB, including cost sharing amounts attributable to EHB, by reducing total claims amounts by the plan-specific percentage estimate of non-essential health benefit claims submitted on the Uniform Rate Review Template for the corresponding benefit year, if the following conditions are met:

(A) The non-essential health benefits percentage estimate is less than 2 percent; and

(B) Out-of-pocket expenses for non-EHB benefits are included in the calculation of amounts subject to a deductible or annual limitation on cost sharing, but copayments and coinsurance rates on non-EHB benefits are not reduced under the plan variation.

(ii) [Reserved]

(3) *Selection of methodology.* For benefit years 2014 through 2016, notwithstanding paragraph (c)(2) of this section, a QHP issuer may choose to calculate the amounts that would have been paid under the standard plan without cost-sharing reductions using the simplified methodology described in paragraph (c)(4) of this section.

(i) The QHP issuer must notify HHS prior to the start of each benefit year, in the manner and timeframe established by HHS, whether or not it selects the simplified methodology for the benefit year.

(ii) If the QHP issuer selects the simplified methodology, it must apply the simplified methodology to all plan variations it offers on the Exchange for a benefit year.

(iii) The QHP issuer may not select the simplified methodology for a benefit year if the QHP issuer did not select the simplified methodology for the prior benefit year.

(iv) Notwithstanding paragraphs (c)(3)(ii) and (iii) of this section, if a QHP issuer merges with or acquires another issuer of a QHP on the Exchange, or acquires a QHP offered on the Exchange from another QHP issuer, and if one, but not all, of the merging, acquiring, or acquired parties had selected the simplified methodology for the benefit year, then for the benefit year in which the merger or acquisition took place, the QHP issuer must calculate the amounts that would have been paid using the methodology (whether the standard methodology described in paragraph (c)(2) of this section or the simplified methodology described in paragraph (c)(4) of this section) selected with respect to the plan variation prior to the start of the benefit year (even if the selection was not made by that QHP issuer). For the next benefit year (if such benefit year is 2015 or 2016), the QHP issuer may select the simplified methodology (subject to paragraph (c)(3)(ii) of this section but, for that benefit year, not paragraph (c)(3)(iii) of this section) or the standard methodology.

(4) *Simplified methodology.* Subject to paragraph (c)(4)(v) of this section, a QHP issuer that selects the simplified methodology described in this paragraph (c)(4) must calculate the amount that the enrollees would have paid under the standard plan without cost-sharing reductions for each policy that was assigned to a plan variation for any portion of the benefit year by applying each set of the standard plan's effective cost-sharing parameters (as calculated under paragraphs (c)(3)(ii) and (iii) of this section) to the corresponding subgroup of total allowed costs for EHB for the policy (as described in paragraph (c)(4)(i) of this section).

(i) For plan variation policies with total allowed costs for EHB for the benefit year that are:

(A) Less than or equal to the effective deductible, the amount that the enrollees would have paid under the standard plan is equal to the total allowed costs for EHB under the policy for the benefit year multiplied by the effective pre-deductible coinsurance rate.

(B) Greater than the effective deductible but less than the effective claims ceiling, the amount that the enrollees would have paid under the standard plan is equal to the sum of (x) the average deductible, plus (y) the effective non-deductible cost sharing, plus (z) the difference, if positive, between the total allowed costs under the policy for

the benefit year for EHB that are subject to a deductible and the average deductible, multiplied by the effective post-deductible coinsurance rate.

(C) Greater than or equal to the effective claims ceiling, the amount that the enrollees would have paid under the standard plan is equal to the annual limitation on cost sharing for the standard plan (as defined at 45 CFR 156.400), or, at the QHP issuer's election on a policy-by-policy basis, the amount calculated pursuant to the standard methodology described in paragraph (c)(2) of this section,

(ii) The QHP issuer must calculate one or more sets of effective cost-sharing parameters, as described in paragraph (c)(4)(iii) of this section, based on policies assigned to the standard plan without cost-sharing reductions for the entire benefit year and must separately apply each set of effective cost-sharing parameters to the corresponding subgroup of total allowed costs for EHB for each plan variation policy, as described in paragraph (c)(4)(i) of this section, as follows:

(A) If the standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage, but does not have separate cost-sharing parameters for pharmaceutical and medical services, the QHP issuer must calculate and apply separate sets of effective cost-sharing parameters based on the costs of enrollees in the standard plan with self-only coverage, and based on the costs of enrollees in the standard plan with other than self-only coverage.

(B) If the standard plan has separate cost-sharing parameters for pharmaceutical and medical services, but does not have separate cost-sharing parameters for self-only coverage and other than self-only coverage, the QHP issuer must calculate and apply separate sets of effective cost-sharing parameters based on the medical costs of the enrollees in the standard plan, and based on the pharmaceutical costs of the enrollees in the standard plan.

(C) If the standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage, and also has separate cost-sharing parameters for pharmaceutical and medical services, the QHP issuer must calculate and apply separate sets of effective cost-sharing parameters based on the medical costs of enrollees in the standard plan with self-only coverage, based on the pharmaceutical costs of enrollees in the standard plan with self-only coverage, based on the medical costs of enrollees in the standard plan with other than self-only coverage, and based on the pharmaceutical costs of enrollees in the standard plan with other than self-only coverage.

(iii) The effective cost-sharing parameters for the standard plan without cost-sharing reductions must be calculated based on policies assigned to the standard plan for the entire benefit year for each of the required subgroups under paragraph (c)(4)(ii) of this section as follows:

(A) If the standard plan has only one deductible (for the applicable subgroup), the average deductible of the standard plan is that deductible amount. If the standard plan has more than one deductible (for the applicable subgroup), the average deductible is the weighted average of the deductibles, weighted by allowed costs for EHB under the standard plan for the benefit year that are subject to each separate deductible. Services that are not subject to any deductible (including services subject to copayments or coinsurance but not any deductible) are not to be incorporated into the calculation of the average deductible.

(B) The effective non-deductible cost sharing for the applicable subgroup is the average portion of total allowed costs for EHB that are not subject to any deductible for the standard plan for the benefit year incurred for standard plan enrollees and payable by the enrollees as cost sharing. The effective non-deductible cost sharing must be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are above the effective deductible but for which associated cost sharing for EHB is less than the annual limitation on cost sharing.

(C) The effective deductible for the applicable subgroup is equal to the sum of the average deductible and the average total allowed costs for EHB that are not subject to any deductible for the standard plan for the benefit year.

The average total allowed costs for EHB that are not subject to any deductible for the standard plan for the benefit year must be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are above the average deductible but for which associated cost sharing for EHB is less than the annual limitation on cost sharing.

(D) The effective pre-deductible coinsurance rate for the applicable subgroup is the proportion of the total allowed costs for EHB under the standard plan for the benefit year incurred for standard plan enrollees and payable as cost sharing. The effective pre-deductible coinsurance rate must be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are less than or equal to the effective deductible.

(E) The effective post-deductible coinsurance rate for the applicable subgroup is the quotient of (x) the portion of average allowed costs for EHB subject to a deductible incurred for enrollees for the benefit year, and payable by the enrollees as cost sharing other than through a deductible, over the difference of (y) the average allowed costs for EHB subject to a deductible incurred for enrollees for the benefit year, and (z) the average deductible. The effective post-deductible coinsurance rate must be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are above the effective deductible but for which associated cost sharing for EHB is less than the annual limitation on cost sharing.

(F) The effective claims ceiling for the applicable subgroup is calculated as the effective deductible plus the quotient of (x) the difference between the annual limitation on cost sharing and the sum of the average deductible and the effective non-deductible cost sharing, divided by (y) the effective post-deductible coinsurance rate.

(iv) If a QHP issuer uses the simplified methodology described in this paragraph (c)(4), and the QHP issuer's standard plan does not meet any of the criteria in paragraphs (c)(4)(v)(A) through (D) of this section, the QHP issuer must also submit to HHS, in the manner and timeframe established by HHS, the following information for each standard plan offered by the QHP issuer in the individual market through the Exchange for each of the required subgroups described in paragraph (c)(4)(ii) of this section:

(A) The average deductible for each applicable subgroup;

(B) The effective deductible for each applicable subgroup;

(C) The effective non-deductible cost sharing amount for each applicable subgroup;

(D) The effective pre-deductible coinsurance rate for each applicable subgroup;

(E) The effective post-deductible coinsurance rate for each applicable subgroup;

(F) The effective claims ceiling for each applicable subgroup; and

(G) A memorandum developed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies that describes how the QHP issuer calculated the effective cost-sharing parameters for each applicable subgroup for the standard plan.

(v) Notwithstanding paragraphs (c)(4)(i) through (iii) of this section, if a QHP issuer's standard plan meets the criteria in any of the following subparagraphs, and the QHP issuer has selected the simplified methodology described in this paragraph (c)(4), then the QHP issuer must calculate the amount that the enrollees in the plan variation would have paid under the standard plan without cost-sharing reductions as the lesser of the annual limitation on cost sharing for the standard plan or the amount equal to the product of, (x) one minus the standard plan's actuarial value, as calculated under 45 CFR 156.135, and (y) the total allowed costs for EHB for the benefit year under each policy that was assigned to a plan variation for any portion of the benefit year.

(A) The standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage, does not have separate cost-sharing parameters for pharmaceutical and medical services, and has an enrollment during the benefit year of fewer than 12,000 member months for

coverage with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing, in either of the following categories –

(1) Self-only coverage; or

(2) Other than self-only coverage.

(B) The standard plan has separate cost-sharing parameters for pharmaceutical and medical services, does not have separate cost-sharing parameters for self-only coverage and other than self-only coverage, and has an enrollment during the benefit year of fewer than 12,000 member months for coverage with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing, in either of the following categories:

(1) Coverage of medical services; or

(2) Coverage of pharmaceutical services.

(C) The standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage and for pharmaceutical and medical services, and has an enrollment during the benefit year of fewer than 12,000 member months for coverage with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing, in any of the following categories:

(1) Self-only coverage of medical services;

(2) Self-only coverage of pharmaceutical services;

(3) Other than self-only coverage of medical services; or

(4) Other than self-only coverage of pharmaceutical services.

(D) The standard plan does not have separate cost-sharing parameters for pharmaceutical and medical services, or for self-only coverage and other than self-only coverage, and has an enrollment during the benefit year of fewer than 12,000 member months with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing.

(vi) Notwithstanding paragraphs (c)(4)(i)(A) and (B) of this section, and paragraphs (c)(4)(iii)(A) through (E) of this section, if more than eighty percent of the total allowed costs for EHB for the benefit year under a standard plan for a subgroup that requires a separate set of effective cost-sharing parameters pursuant to paragraph (c)(4)(ii) are not subject to a deductible, then:

(A) The average deductible, the effective non-deductible cost sharing, and the effective deductible for the subgroup equal zero;

(B) The effective pre-deductible coinsurance rate for the subgroup is equal to the effective post-deductible coinsurance rate for the subgroup, which is determined based on all standard plan policies for the applicable subgroup for which associated cost sharing for EHB is less than the annual limitation on cost sharing, and calculated for the applicable subgroup as the proportion of the total allowed costs for EHB under the standard plan for the benefit year incurred for standard plan enrollees and payable as cost sharing (including cost sharing payable through a deductible); and

(C) The amount that enrollees in the applicable subgroup in plan variation policies with total allowed costs for EHB for the benefit year that are less than the effective claims ceiling would have paid under the standard plan must be calculated using the formula in paragraph (c)(4)(i)(A).

(5) *Reimbursement of providers.* In the case of a benefit for which the QHP issuer compensates an applicable provider in whole or in part on a fee-for-service basis, allowed costs associated with the benefit may be included in the calculation of the amount that an enrollee(s) would have paid under the standard plan without cost-sharing reductions only to the extent the amount was either payable by the enrollee(s) as cost sharing under the plan variation or was reimbursed to the provider by the QHP issuer.

(d) *Cost-sharing reductions data submissions.* HHS will periodically provide

a submission window for issuers to submit cost-sharing reduction data documenting cost-sharing reduction amounts issuers paid, as specified in paragraphs (d)(1) and (2) of this section, in a form and manner specified by HHS in guidance, calculated in accordance with paragraph (c) of this section. When HHS makes cost-sharing reduction payments to QHP issuers, HHS will notify QHP issuers that the submission of the cost-sharing data is mandatory for those issuers having received cost-sharing reduction payments for any part of the benefit year and voluntary for other issuers, and HHS will use the data to reconcile advance cost-sharing reduction payments to issuers against the actual amounts of cost-sharing reductions QHP issuers provided, as determined by HHS based on amounts specified in paragraphs (d)(1) and (2) of this section, as calculated in accordance with paragraph (c) of this section. In the absence of an appropriation to make cost-sharing reduction payments to issuers, HHS will notify QHP issuers that the submission of the cost-sharing data is voluntary. The cost-sharing data that must be submitted in either a voluntary or mandatory submission includes:

(1) The actual amount of cost-sharing reductions provided to enrollees and reimbursed to providers by the QHP issuer for benefits for which the QHP issuer compensates the applicable providers in whole or in part on a fee-for-service basis; and

(2) The actual amount of cost-sharing reductions provided to enrollees for benefits for which the QHP issuer compensates the applicable providers in any other manner.

(e) *Cost-sharing reductions payments and charges.* If the actual amounts of cost-sharing reductions determined by HHS based on amounts described in paragraphs (d)(1) and (2) of this section are—

(1) More than the amount of advance payments HHS provided, and the QHP issuer has timely provided the data of actual amounts of cost-sharing reductions as required under paragraph (c) of this section, if an appropriation is available to make cost-sharing payments to QHP issuers, HHS will make a payment to the QHP issuer for the difference; or

(2) Less than the amount of advance payments provided, the QHP issuer must repay the difference to HHS in the manner and timeframe specified by HHS.

(f) *Cost-sharing reductions during special periods.* (1) Notwithstanding the cost-sharing reduction reconciliation process described in paragraphs (c) through (e) of this section, a QHP issuer will not be eligible for reimbursement of any cost-sharing reductions provided following a termination of coverage effective date with respect to a grace period as described in §155.430(b)(2)(ii)(A) or (B) of this subchapter. However, the QHP issuer will be eligible for reimbursement of cost-sharing reductions provided prior to the termination of coverage effective date. Advance payments of cost-sharing reductions will be paid to a QHP issuer prior to a determination of termination (including during any grace period, but the QHP issuer will be required to repay any advance payments made with respect to any month after any termination of coverage effective date during a grace period).

(2) Notwithstanding the cost-sharing reduction reconciliation process described in paragraphs (c) through (e) of this section, if the termination of coverage effective date is prior to the determination of termination other than in the circumstances described in paragraph (f)(1) of this section, and if the termination (or the late determination thereof) is the fault of the QHP issuer, as reasonably determined by the Exchange, the QHP issuer will not be eligible for advance payments and reimbursement for cost-sharing reductions provided during the period following the termination of coverage effective date and prior to the determination of the termination.

(3) Subject to the requirements of the cost-sharing reduction reconciliation process described in paragraphs (c) through (e) of this section, if the termination of coverage effective date is prior to the determination of termination other than in the circumstances described in paragraph (f)(1) of this section, and if the reason for the termination (or late determination thereof)

is not the fault of the QHP issuer, as reasonably determined by the Exchange, the QHP issuer will be eligible for advance payments and reimbursement for cost-sharing reductions provided during such period.

(4) Subject to the requirements of the cost-sharing reduction reconciliation process described in paragraphs (c) through (e) of this section, a QHP issuer will be eligible for advance payments and reimbursement for cost-sharing reductions provided during any period of coverage pending resolution of inconsistencies in information required to determine eligibility for enrollment under §155.315(f) of this subchapter.

(g) *Prohibition on reduction in payments to Indian health providers.* If an Indian is enrolled in a QHP in the individual market through an Exchange and is furnished an item or service directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization, or through referral under contract health services, the QHP issuer may not reduce the payment to any such entity for such item or service by the amount of any cost sharing that would be due from the Indian but for the prohibitions on cost sharing set forth in §156.410(b)(2) and (3).

(h) *Reconciliation of the cost-sharing reduction portion of advance payments discrepancies and appeals.* (1) If an issuer reports a discrepancy and seeks to dispute the notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments, it must report the discrepancy to HHS within 30 calendar days of notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments as described in paragraph (e) of this section, in the manner set forth by HHS.

(2) An issuer may appeal the amount of reconciliation of the cost-sharing reduction portion of advance payments, under the process set forth in §156.1220.

[78 FR 15535, 15555, Mar. 11, 2013, as amended at 78 FR 65097, Oct. 30, 2013; 79 FR 13840, Mar. 11, 2014; 80 FR 10875, Feb. 27, 2015; 81 FR 94181, Dec. 22, 2016; 87 FR 27392, May 6, 2022]

§156.440 Plans eligible for advance payments of the premium tax credit and cost-sharing reductions.

Except as noted in paragraph (a) through (c) of this section, the provisions of this subpart apply to qualified health plans offered in the individual market on the Exchange.

(a) *Catastrophic plans.* The provisions of this subpart do not apply to catastrophic plans described in §156.155.

(b) *Stand-alone dental plans.* The provisions of this subpart, to the extent relating to cost-sharing reductions, do not apply to stand-alone dental plans. The provisions of this subpart, to the extent relating to advance payments of the premium tax credit, apply to stand-alone dental plans.

(c) *Child-only plans.* The provisions of this subpart apply to child-only QHPs, described in §156.200(c)(2).

§156.460 Reduction of enrollee's share of premium to account for advance payments of the premium tax credit.

(a) *Reduction of enrollee's share of premium to account for advance payments of the premium tax credit.* A QHP issuer that receives notice from the Exchange that an individual enrolled in the issuer's QHP is eligible for an advance payment of the premium tax credit must—

(1) Reduce the portion of the premium charged to or for the individual for the applicable month(s) by the amount of the advance payment of the premium tax credit;

(2) Notify the Exchange of the reduction in the portion of the premium charged to the individual in accordance with §156.265(g); and

(3) Include with each billing statement, as applicable, to or for the individual the amount of the advance payment of the premium tax credit for the applicable month(s), and the remaining premium owed.

(b) *Delays in payment.* A QHP issuer may not refuse to commence coverage under a policy or terminate coverage on account of any delay in payment of an advance payment of the premium tax credit on behalf of an enrollee if the QHP issuer has been notified by the

Exchange under §155.340(a) of this subchapter that the QHP issuer will receive such advance payment.

(c) *Refunds to enrollees for improper reduction of enrollee's share of premium to account for advance payments of the premium tax credit.* If a QHP issuer discovers that it did not reduce the portion of the premium charged to or for an enrollee for the applicable month(s) by the amount of the advance payment of the premium tax credit in accordance with paragraph (a)(1) of this section, the QHP issuer must notify the enrollee of the improper reduction within 45 calendar days of the QHP issuer's discovery of the improper reduction and refund any excess premium paid by or for the enrollee, as follows:

(1) Unless a refund is requested by or for the enrollee, the QHP issuer must, within 45 calendar days of discovery of the error, apply the excess premium paid by or for the enrollee to the enrollee's portion of the premium (or refund the amount directly). If any excess premium remains, the QHP issuer must apply the excess premium to the enrollee's portion of the premium for each subsequent month for the remainder of the period of enrollment or benefit year until the excess is fully applied (or refund the remaining amount directly). If any excess premium remains at the end of the period of enrollment or benefit year, the QHP issuer must refund any excess premium within 45 calendar days of the end of the period of enrollment or benefit year, whichever comes first.

(2) If a refund is requested by or for the enrollee, the refund must be provided within 45 calendar days of the date of the request.

[78 FR 15535, Mar. 11, 2013, as amended at 78 FR 65100, Oct. 30, 2013]

§ 156.470 Allocation of rates for advance payments of the premium tax credit.

(a) *Allocation to additional health benefits for QHPs.* An issuer must provide to the Exchange annually for approval, in the manner and timeframe established by HHS, for each health plan at any level of coverage offered, or intended to be offered, in the individual market on an Exchange, an allocation of the rate for the plan to:

(1) EHB, other than services described in §156.280(d)(1); and

(2) Any other services or benefits offered by the health plan not described in paragraph (a)(1) of this section.

(b) *Allocation to additional health benefits for stand-alone dental plans.* An issuer must provide to the Exchange annually for approval, in the manner and timeframe established by HHS, for each stand-alone dental plan offered, or intended to be offered, in the individual market on the Exchange, a dollar allocation of the expected premium for the plan, to:

(1) The pediatric dental essential health benefit, and

(2) Any benefits offered by the stand-alone dental plan that are not the pediatric dental essential health benefit.

(c) *Allocation standards for QHPs.* The issuer must ensure that the allocation described in paragraph (a) of this section—

(1) Is performed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies;

(2) Reasonably reflects the allocation of the expected allowed claims costs attributable to EHB (excluding those services described in §156.280(d)(1));

(3) Is consistent with the allocation applicable to State-required benefits to be submitted by the issuer under §155.170(c) of this subchapter, and the allocation requirements described in §156.280(e)(4) for certain services; and

(4) Is calculated under the fair health insurance premium standards described at 45 CFR 147.102, the single risk pool standards described at 45 CFR 156.80, and the same premium rate standards described at 45 CFR 156.255.

(d) *Allocation standards for stand-alone dental plans.* The issuer must ensure that the dollar allocation described in paragraph (b) of this section is performed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies.

(e) *Disclosure of attribution and allocation methods.* An issuer of a health plan at any level of coverage or a stand-alone dental plan offered, or intended to be offered, in the individual market on the Exchange must submit to the

Exchange annually for approval, an actuarial memorandum, in the manner and timeframe specified by HHS, with a detailed description of the methods and specific bases used to perform the allocations set forth in paragraphs (a) and (b), and demonstrating that the allocations meet the standards set forth in paragraphs (c) and (d) of this section, respectively.

(f) *Multi-State plans.* Issuers of multi-State plans, as defined in §155.1000(a) of this subchapter, must submit the allocations and actuarial memorandum described in this section to the U.S. Office of Personnel Management, in the time and manner established by the U.S. Office of Personnel Management.

[78 FR 15535, Mar. 11, 2013, as amended at 79 FR 13840, Mar. 11, 2014]

§ 156.480 Oversight of the administration of the advance payments of the premium tax credit, cost-sharing reductions, and user fee programs.

(a) *Maintenance of records.* An issuer that offers a QHP in the individual market through a State Exchange must adhere to, and ensure that any relevant delegated entities and downstream entities adhere to, the standards set forth in §156.705 concerning maintenance of documents and records, whether paper, electronic, or in other media, by issuers offering QHPs in a Federally-facilitated Exchange, in connection with cost-sharing reductions and advance payments of the premium tax credit.

(b) *Annual reporting requirements.* For each benefit year, an issuer that offers a QHP in the individual market through an Exchange must report to HHS, in the manner and timeframe required by HHS, summary statistics specified by HHS with respect to administration of cost-sharing reduction and advance payments of the premium tax credit programs, including any failure to adhere to the standards set forth under §§156.410(a) through (d), 156.425(a) through (b), and 156.460(a) through (c) of this part.

(c) *Audits and compliance reviews.* HHS or its designee may audit or conduct a compliance review of an issuer offering a QHP through an Exchange to assess its compliance with the applicable requirements of this subpart and 45 CFR 156.50. Compliance reviews conducted under this section will follow the standards set forth in §156.715.

(1) *Notice of audit.* HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer under this section.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with audit activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference described under paragraph (c)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraph (c)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraph (c)(2)(ii) or (iii), as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary audit findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to

such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final audit findings.* If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 45 calendar days of the issuance of the final audit or compliance review report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to comply with audit activities.* If an issuer fails to comply with the audit activities set forth in this section in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of payments received under this subpart that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any payments identified in paragraph (c)(5)(i) of this section.

(6) *Circumstances requiring HHS enforcement.* If HHS determines that the State Exchange or State-based Exchange on the Federal platform is not enforcing or fails to substantially enforce the requirements of this subpart or § 156.50, then HHS may do so and may pursue the imposition of civil money penalties as specified in § 156.805 for non-compliance by QHP issuers participating in the State Exchange or State Exchange on the Federal platform.

[78 FR 65100, Oct. 30, 2013, as amended at 86 FR 24292, May 5, 2021]

Subpart F—Consumer Operated and Oriented Plan Program

§ 156.500 Basis and scope.

This subpart implements section 1322 of the Affordable Care Act by establishing the Consumer Operated and Oriented Plan (CO–OP) program to foster the creation of new consumer-governed, private, nonprofit health insurance issuers, known as ''CO–OPs.'' Under this program, loans are awarded to encourage the development of CO–OPs. Applicants that meet the eligibility standards of the CO–OP program may apply to receive loans to help fund start-up costs and meet the solvency requirements of States in which the applicant seeks to be licensed to issue CO–OP qualified health plans. This subpart sets forth the eligibility and governance requirements for the CO–OP program, CO–OP standards, and the terms for loans awarded under the CO–OP program.

§ 156.505 Definitions.

The following definitions apply to this subpart:

Applicant means an entity eligible to apply for a loan described in § 156.520 of this subpart.

Consumer operated and oriented plan (CO–OP) means a loan recipient that satisfies the standards in section 1322(c) of the Affordable Care Act and § 156.515 of this subpart within the timeframes specified in this subpart.

CO–OP qualified health plan means a health plan that has in effect a certification that it meets the standards described in subpart C of this part, except that the plan can be deemed certified by CMS or an entity designated by CMS as described in § 156.520(e).

Exchange has the meaning given to the term in § 155.20 of this subchapter.

Formation board means the initial board of directors of the applicant or loan recipient before it has begun accepting enrollment and had an election by the members of the organization to the board of directors.

Individual market has the meaning given to the term in § 155.20 of this subchapter.

Issuer has the meaning given to the term in § 155.20 of this subchapter.

Member means an individual covered under health insurance policies issued by a loan recipient.

Nonprofit member organization or *nonprofit member corporation* means a nonprofit, not-for-profit, public benefit, or similar membership entity organized as appropriate under State law.

Operational board means the board of directors elected by the members of the loan recipient after it has begun accepting enrollment.

Predecessor, with respect to a new entity, means any entity that participates in a merger, consolidation, purchase or acquisition of property or stock, corporate separation, or other similar business transaction that results in the formation of the new entity.

Pre-existing issuer means a health insurance issuer licensed by a State regulator that marketed individual or group health insurance benefit plans (other than Medicare or Medicaid Managed Care plans) on July 16, 2009.

Qualified nonprofit health insurance issuer means an entity that satisfies or can reasonably be expected to satisfy the standards in section 1322(c) of the Affordable Care Act and §156.515 of this subpart within the time frames specified in this subpart, until such time as CMS determines the entity does not satisfy or cannot reasonably be expected to satisfy these standards.

Related entity means an entity that shares common ownership, control, or governance structure (including management team or Board members) with a pre-existing issuer, and satisfies at least one of the following conditions:

(1) Retains responsibilities for the services to be provided by the issuer.

(2) Furnishes services to the issuer's enrollees under an oral or written agreement.

(3) Performs some of the issuer's management functions under contract or delegation.

Representative means an officer, director, or trustee of an organization, or group of organizations; or a senior executive or high-level representative of the Federal government, or a State or local government or a sub-unit thereof.

SHOP has the meaning given to the term in §155.20 of this subchapter.

Small group market has the meaning given to the term in §155.20 of this subchapter.

Solvency Loan means a loan provided by CMS to a loan recipient in order to meet State solvency and reserve requirements.

Sponsor means an organization or individual that is involved in the development, creation, or organization of the CO–OP or provides 40 percent or more in total funding to a CO–OP (excluding any loans received from the CO–OP Program).

Start-up Loan means a loan provided by CMS to a loan recipient for costs associated with establishing a CO–OP.

State has the meaning given to the term in §155.20 of this subchapter.

[76 FR 77411, Dec. 13, 2011, as amended at 77 FR 18474, Mar. 27, 2012; 81 FR 29155, May 11, 2016; 81 FR 94181, Dec. 22, 2016]

§ 156.510 Eligibility.

(a) *General.* In addition to the eligibility standards set forth in the CO–OP program Funding Opportunity Announcement (FOA), to be eligible to apply for and receive a loan under the CO–OP program, an organization must intend to become a CO–OP and be a nonprofit member organization.

(b) *Exclusions from eligibility.* (1) Subject to paragraph (b)(2) of this section, an organization is not eligible to apply for a loan if:

(i) The organization or a sponsor of the organization is a pre-existing issuer, a holding company (an organization that exists primarily to hold stock in other companies) that controls a pre-existing issuer, a trade association comprised of pre-existing issuers and whose purpose is to represent the interests of the health insurance industry, a foundation established by a pre-existing issuer, a related entity, or a predecessor of either a pre-existing issuer or related entity;

(ii) The organization receives 25 percent or more of its total funding (excluding any loans received from the CO–OP Program) from pre-existing issuers, holding companies (organizations that exists primarily to hold stock in other companies) that control pre-existing issuers, trade associations comprised of pre-existing issuers and

whose purpose is to represent the interests of the health insurance industry, foundations established by a pre-existing issuer, a related entity, or a predecessor of either a pre-existing issuer or related entity; or

(iii) A State or local government, any political subdivision thereof, or any instrumentality of such government or political subdivision is a sponsor of the organization. The organization receives 40 percent or more of its total funding (excluding any loans received from the CO–OP Program) from a State or local government, any political subdivision thereof, or any instrumentality of such a government or political subdivision.

(2) The exclusions in paragraphs (b)(1)(i) and (b)(1)(ii) of this section do not exclude from eligibility an applicant that:

(i) Has as a sponsor a nonprofit, not-for-profit, public benefit, or similarly organized entity that is also a sponsor for a pre-existing issuer but is not an issuer, a foundation established by a pre-existing issuer, a holding company that controls a pre-existing issuer, or a trade association comprised of pre-existing issuers and whose purpose is to represent the interests of the health insurance industry, provided that the pre-existing issuer sponsored by the nonprofit organization does not share any of its board or the same chief executive with the applicant; or

(ii) Has purchased assets from a pre-existing issuer provided that it is an arm's-length transaction where each party acts independently and has no other relationship with the other party.

(3) The exclusion of any instrumentality of a State or local government in paragraph (b)(1)(iii) of this section does not exclude from eligibility or sponsorship an organization that:

(i) Is not a government organization under State law;

(ii) Has no employee of a State or local government serving in his or her official capacity as a senior executive (for example, President, Chief Executive Officer, or Chief Financial Officer) for the organization; and

(iii) Has a board of directors on which fewer than half of its directors are employees of a State or local government serving in their official capacities.

[76 FR 77411, Dec. 13, 2011, as amended at 77 FR 18474, Mar. 27, 2012]

§ 156.515 CO–OP standards.

(a) *General.* A CO–OP must satisfy the standards in this section in addition to all other statutory, regulatory, or other requirements.

(b) *Governance requirements.* A CO–OP must meet the following governance requirements:

(1) *Member control.* A CO–OP must implement policies and procedures to foster and ensure member control of the organization. Accordingly, a CO–OP must meet the following requirements:

(i) The CO–OP must be governed by an operational board with a majority of directors elected by a majority vote of a quorum of the CO–OP's members that are age 18 or older;

(ii) All members age 18 or older must be eligible to vote for each of the directors on the organization's operational board subject to a vote of the members under paragraph (b)(1)(i) of this section;

(iii) Each member age 18 or older must have one vote in each election for each director subject to a vote of the members under paragraph (b)(1)(i) of this section in that election;

(iv) The first elected directors of the organization's operational board must be elected no later than one year after the effective date on which the organization provides coverage to its first member; the entire operational board must be elected or in place, and in full compliance with paragraph (b)(1)(i) of this section, no later than two years after the same date;

(v) Elections of the directors on the organization's operational board subject to a vote of the members under paragraph (b)(1)(i) of this section must be contested so that the total number of candidates for contested seats on the operational board exceeds the number of contested seats for such directors, except in cases where a seat is vacated mid- term due to death, resignation, or removal.

(2) *Standards for board of directors.* The operational board for a CO–OP must meet the following standards:

(i) Each director must meet ethical, conflict-of-interest, and disclosure standards;

(ii) Each director has one vote;

(iii) Positions on the board of directors may be designated for individuals with specialized expertise, experience, or affiliation (for example, providers, employers, and unions); and

(iv) [Reserved]

(v) *Limitation on government and issuer participation.* No representative of any Federal, State or local government (or of any political subdivision or instrumentality thereof) and no representative of any organization described in §156.510(b)(1)(i) (in the case of a representative of a State or local government or organization described in §156.510(b)(1)(i), with respect to a State in which the CO–OP issues policies), may serve on the CO–OP's formation board or as a director on the organization's operational board.

(3) *Ethics and conflict of interest protections.* The CO–OP must have governing documents that incorporate ethics, conflict of interest, and disclosure standards. The standards must protect against insurance industry involvement and interference. In addition, the standards must ensure that each director acts in the sole interest of the CO–OP, its members, and its local geographic community as appropriate, avoids self dealing, and acts prudently and consistently with the terms of the CO–OP's governance documents and applicable State and Federal law. At a minimum, these standards must include:

(i) A mechanism to identify potential ethical or other conflicts of interest;

(ii) A duty on the CO–OP's executive officers and directors to disclose all potential conflicts of interest;

(iii) A process to determine the extent to which a conflict exists;

(iv) A process to address any conflict of interest; and

(v) A process to be followed in the event a director or executive officer of the CO–OP violates these standards.

(4) *Consumer focus.* The CO–OP must operate with a strong consumer focus, including timeliness, responsiveness, and accountability to members.

(c) *Standards for health plan issuance.* A CO–OP must meet several standards for the issuance of health plans in the individual and small group market.

(1) At least two-thirds of the policies or contracts for health insurance coverage issued by a CO–OP in each State in which it is licensed must be CO–OP qualified health plans offered in the individual and small group markets.

(2) Loan recipients must offer a CO–OP qualified health plan at the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in every individual market Exchange that serves the geographic regions in which the organization is licensed and intends to provide health care coverage. If offering at least one plan in the small group market, loan recipients must offer a CO–OP qualified health plan at both the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in each SHOP that serves the geographic regions in which the organization offers coverage in the small group market.

(3) Within the earlier of thirty-six months following the initial drawdown of the Start-up Loan or one year following the initial drawdown of the Solvency Loan, loan recipients must be licensed in a State and offer at least one CO–OP qualified health plan at the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in the individual market Exchanges and if the loan recipient offers coverage in the small group market, at the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in the SHOPs. Loan recipients may only begin offering plans and accepting enrollment in the Exchanges for new CO–OP qualified health plans during the open enrollment period for each applicable Exchange.

(d) *Requirement to become a CO–OP.* Loan recipients must meet the standards of §156.515 no later than five years following initial drawdown of the Start-up Loan or three years following the initial drawdown of a Solvency Loan.

[76 FR 77411, Dec. 13, 2011, as amended at 81 FR 29155, May 11, 2016; 81 FR 94182, Dec. 22, 2016]

§ 156.520 Loan terms.

(a) *Overview of Loans.* Applicants may apply for the following loans under this section: Start-up Loans and Solvency Loans.

(1) *Use of loans.* All loans awarded under this subpart must be used in a manner that is consistent with the FOA, the loan agreement, and all other statutory, regulatory, or other requirements.

(2) *Solvency loans.* Solvency Loans awarded under this section will be structured in a manner that ensures that the loan amount is recognized by State insurance regulators as contributing to the State-determined reserve requirements or other solvency requirements (rather than debt) consistent with the insurance regulations for the States in which the loan recipient will offer a CO–OP qualified health plan.

(b) *Repayment period.* The loan recipient must make loan payments consistent with the approved repayment schedule in the loan agreement until the loan is paid in full consistent with State reserve requirements, solvency regulations, and requisite surplus note arrangements. Subject to their ability to meet State reserve requirements, solvency regulations, or requisite surplus note arrangements, the loan recipient must repay its loans and, if applicable, penalties within the repayment periods in paragraphs (b)(1), (b)(2), or (b)(3) of this section.

(1) The contractual repayment period for Start-up Loans and any applicable penalty pursuant to paragraph (c)(3) of this section is 5 years following each drawdown of loan funds consistent with the terms of the loan agreement.

(2) The contractual repayment period for Solvency Loans and any applicable penalty pursuant to paragraph (c)(3) of this section is 15 years following each drawdown of loan funds consistent with the terms of the loan agreement.

(3) Changes to the loan terms, including the repayment periods, may be executed if CMS determines that the loan recipient is unable to repay the loans as a result of State reserve requirements, solvency regulations, or requisite surplus note arrangements or without compromising coverage stability, member control, quality of care, or market stability. In the case of a loan modification or workout, the repayment period for loans awarded under this subpart is the repayment period established in the loan modification or workout. The revised terms must meet all other regulatory, statutory, and other requirements.

(c) *Interest rates.* Loan recipients will be charged interest for the loans awarded under this subpart. Interest will be accrued starting from the date of drawdown on the loan amounts that have been drawn down and not yet repaid by the loan recipient. The interest rate will be determined based on the date of award.

(1) *Start-up Loans.* Consistent with the terms of the loan agreement, the interest rate for Start-up Loans is equal to the greater of the average interest rate on marketable Treasury securities of similar maturity minus one percentage point or zero percent. If the loan recipient's loan agreement is terminated by CMS, the loan recipient will be charged the interest and penalty described in paragraph (c)(3) of this section.

(2) *Solvency Loans.* Consistent with the terms of the loan agreement, the interest rate for Solvency Loans is equal to the greater of the average interest rate on marketable Treasury securities of similar maturity minus two percentage points or zero percent. If a loan recipient's loan agreement is terminated by CMS, the loan recipient will be charged the interest and penalty described in paragraph (c)(3) of this section.

(3) *Penalty payment.* If CMS terminates a loan recipient's loan agreement because the loan recipient is not in compliance with program rules or the terms of its loan agreement, or CMS has reason to believe that the organization engages in, or has engaged in, criminal or fraudulent activities or activities that cause material harm to the organization's members or the government, the loan recipient must repay 110 percent of the aggregate amount of loans received under this subpart. In addition, the loan recipient must pay interest on the aggregate amount of loans received for the period the loans were outstanding equal to the average

interest rate on marketable Treasury securities of similar maturity.

(d) *Failure to pay.* Loan recipients that fail to make loan payments consistent with the repayment schedule or loan modification or workout approved by CMS will be subject to any and all remedies available to CMS under law to collect the debt.

(e) *Deeming of CO–OP qualified health plans.* Health plans offered by a loan recipient may be deemed certified as a CO–OP qualified health plan to participate in the Exchanges for two years and may be recertified every two years for up to ten years following the life of any loan awarded to the loan recipient under this subpart, consistent with section 1301(a)(2) of the Affordable Care Act.

(1) To be deemed as certified to participate in the Exchanges, the plan must comply with the standards for CO–OP qualified health plans set forth pursuant to section 1311(c) of the Affordable Care Act, all State-specific standards established by an Exchange for qualified health plans operating in that Exchange, except for those State-specific standards that operate to exclude loan recipients due to being new issuers or based on other characteristics that are inherent in the design of a CO–OP, and the standards of the CO–OP program as set forth in this subpart.

(2) A loan recipient seeking to have a plan deemed as certified to participate in the Exchanges must provide evidence to CMS or an entity designated by CMS that the plan complies with the standards for CO–OP qualified health plans set forth pursuant to section 1311(c) of the Affordable Care Act, all State-specific standards established by an Exchange for qualified health plans operating in that Exchange, except for those State-specific standards that operate to exclude loan recipients due to being new issuers or based on other characteristics that are inherent in the design of a CO–OP, and the standards of the CO–OP program as set forth in this subpart.

(3) If a plan offered by a loan recipient is deemed to be certified to participate in the Exchanges or loses its deemed status and is no longer certified to participate in the Exchanges, CMS or an entity designated by CMS will provide notice to the Exchanges in which the loan recipient offers CO–OP qualified health plans.

(f) *Conversions and voluntary terminations.* (1) The loan recipient shall not convert or sell to a for-profit or nonconsumer operated entity at any time after receiving a loan under this subpart. The loan recipient shall not undertake any transaction that would result in the CO–OP implementing a governance structure that does not meet the standards in this subpart.

(2) CMS may, in its sole discretion, approve a request by a loan recipient to voluntarily terminate its loan agreement with CMS, and cease to constitute a QNHII, for the purpose of permitting a loan recipient to pursue innovative business plans that are not otherwise consistent with the requirements of this subpart, provided that all outstanding CO–OP loans issued to the loan recipient are repaid in full prior to termination of the loan agreement, and CMS believes granting the request would meaningfully enhance consumer access to quality, affordable, member-focused, non-profit health care options in affected markets.

[76 FR 77411, Dec. 13, 2011, as amended at 77 FR 18474, Mar. 27, 2012; 89 FR 26426, Apr. 15, 2024]

Subpart G—Minimum Essential Coverage

SOURCE: 78 FR 39529, July 1, 2013, unless otherwise noted.

§ 156.600 The definition of minimum essential coverage.

The term *minimum essential coverage* has the same meaning as provided in section 5000A(f) of the Code and its implementing regulations for purposes of this subpart.

§ 156.602 Other coverage that qualifies as minimum essential coverage.

The following types of coverage are designated by the Secretary as minimum essential coverage for purposes of section 5000A(f)(1)(E) of the Code:

(a) *Self-funded student health coverage.* Coverage offered to students by an institution of higher education (as defined in the Higher Education Act of

1965), where the institution assumes the risk for payment of claims, are designated as minimum essential coverage for plan or policy years beginning on or before December 31, 2014. For coverage beginning after December 31, 2014, sponsors of self-funded student health coverage may apply to be recognized as minimum essential coverage pursuant to the process provided under 45 CFR 156.604.

(b) *Refugee Medical Assistance supported by the Administration for Children and Families.* Coverage under Refugee Medical Assistance, authorized under section 412(e)(7)(A) of The Immigration and Nationality Act, provides up to eight months of coverage to certain noncitizens who are considered Refugees, as defined in section 101(a)(42) of the Act.

(c) *Medicare advantage plans.* Coverage under the Medicare program pursuant to Part C of title XVIII of the Social Security Act, which provides Medicare Parts A and B benefits through a private insurer.

(d) *State high risk pool coverage.* A qualified high risk pool as defined by section 2744(c)(2) of the Public Health Service Act established on or before November 26, 2014 in any State.

(e) *Other coverage.* Other coverage that qualifies pursuant to §156.604.

[78 FR 39529, July 1, 2013, as amended at 80 FR 10875, Feb. 27, 2015]

§ 156.604 Requirements for recognition as minimum essential coverage for types of coverage not otherwise designated minimum essential coverage in the statute or this subpart.

(a) The Secretary may recognize ''other coverage'' as minimum essential coverage provided HHS determines that the coverage meets the following substantive and procedural requirements:

(1) *Coverage requirements.* A plan must meet substantially all the requirements of title I of the Affordable Care Act pertaining to non-grandfathered, individual health insurance coverage.

(2) *Procedural requirements for recognition as minimum essential coverage.* To be considered for recognition as minimum essential coverage, the sponsor of the coverage, government agency, health insurance issuer, or plan administrator must submit the following information to HHS:

(i) Identity of the plan sponsor and appropriate contact persons;

(ii) Basic information about the plan, including:

(A) Name of the organization sponsoring the plan;

(B) Name and title of the individual who is authorized to make, and makes, this certification on behalf of the organization;

(C) Address of the individual named above;

(D) Phone number of the individual named above;

(E) Number of enrollees;

(F) Eligibility criteria;

(G) Cost sharing requirements, including deductible and out-of-pocket maximum limit;

(H) Essential health benefits covered; and

(I) A certification by the appropriate individual, named pursuant to paragraph (a)(3)(ii)(b), that the organization substantially complies with the requirements of title I of the Affordable Care Act that apply to non-grandfathered plans in the individual market and any plan documentation or other information that demonstrate that the coverage substantially comply with these requirements.

(b) CMS will publish a list of types of coverage that the Secretary has recognized as minimum essential coverage pursuant to this provision.

(c) If at any time the Secretary determines that a type of coverage previously recognized as minimum essential coverage no longer meets the coverage requirements of paragraph (a)(1) of this section, the Secretary may revoke the recognition of such coverage.

(d) *Notice.* Once recognized as minimum essential coverage, the sponsor of the coverage, government agency, health insurance issuer, or plan administrator must provide notice to all enrollees of its minimum essential coverage status and must comply with the information reporting requirements of section 6055 of the Internal Revenue Code and implementing regulations.

[78 FR 39529, July 1, 2013, as amended at 79 FR 30351, May 27, 2014]

§ 156.606 HHS audit authority.

The Secretary may audit a plan or program recognized as minimum essential coverage under § 156.604 at any time to ensure compliance with the requirements of § 156.604(a).

Subpart H—Oversight and Financial Integrity Standards for Issuers of Qualified Health Plans in Federally-Facilitated Exchanges

SOURCE: 78 FR 65100, Oct. 30, 2013, unless otherwise noted.

§ 156.705 Maintenance of records for Federally-facilitated Exchanges.

(a) *General standard.* Issuers offering QHPs in a Federally-facilitated Exchange must maintain all documents and records (whether paper, electronic, or other media) and other evidence of accounting procedures and practices, necessary for HHS to do the following:

(1) Periodically audit financial records related to QHP issuers' participation in a Federally-facilitated Exchange, and evaluate the ability of QHP issuers to bear the risk of potential financial losses; and

(2) Conduct compliance reviews or otherwise monitor QHP issuers' compliance with all Exchange standards applicable to issuers offering QHPs in a federally-facilitated Exchange as listed in this part.

(b) *Records.* The records described in paragraph (a) of this section include the sources listed in § 155.1210(b)(2), (3), and (5) of this subchapter.

(c) *Record retention timeframe.* Issuers offering QHPs in a Federally-facilitated Exchange must maintain all records referenced in paragraph (a) of this section for 10 years.

(d) *Record availability.* Issuers offering QHPs in a Federally-facilitated Exchange must make all records in paragraph (a) of this section available to HHS, the OIG, the Comptroller General, or their designees, upon request.

§ 156.715 Compliance reviews of QHP issuers in Federally-facilitated Exchanges.

(a) *General standard.* Issuers offering QHPs in a Federally-facilitated Exchange may be subject to compliance reviews to ensure ongoing compliance with Exchange standards applicable to issuers offering QHPs in a Federally-facilitated Exchange.

(b) *Records.* In preparation for or in the course of the compliance review, a QHP issuer must make available for HHS to review the records of the QHP issuer that pertain to its activities within a Federally-facilitated Exchange. Such records may include, but are not limited to the following:

(1) The QHP issuer's books and contracts, including the QHP issuer's policy manuals and other QHP plan benefit information provided to the QHP issuer's enrollees;

(2) The QHP issuer's policies and procedures, protocols, standard operating procedures, or other similar manuals related to the QHP issuer's activities in a Federally-facilitated Exchange;

(3) Any other information reasonably necessary for HHS to—

(i) Evaluate the QHP issuer's compliance with QHP certification standards and other Exchange standards applicable to issuers offering QHPs in a Federally-facilitated Exchange;

(ii) Evaluate the QHP's performance, including its adherence to an effective compliance plan, within a Federally-facilitated Exchange;

(iii) Verify that the QHP issuer has performed the duties attested to as part of the QHP certification process; and

(iv) Assess the likelihood of fraud or abuse.

(c) *Interest of Qualified Individuals and Qualified Employers.* HHS's findings from the compliance reviews under this section may be in conjunction with other findings related to the QHP issuers' compliance with certification standards, used to confirm that permitting the issuer's QHPs to be available through a Federally-facilitated Exchange is in the interest of the qualified individuals and qualified employers as provided under § 155.1000(c)(2) of this subchapter.

(d) *Onsite and desk reviews.* The QHP issuer will make available, for the purposes listed in paragraph (c) of this section, its premises, physical facilities and equipment (including computer and other electronic systems), for HHS

to conduct a compliance review as provided under this section.

(1) A compliance review under this section will be carried out as an onsite or desk review based on the specific circumstances.

(2) Unless otherwise specified, nothing in this section is intended to preempt Federal laws and regulations related to information privacy and security.

(e) *Compliance review timeframe.* A QHP issuer may be subject to a compliance review up to 10 years from the last day of that plan benefit year, or 10 years from the last day that the QHP certification is effective if the QHP is no longer available through a Federally-facilitated Exchange; provided, however, that if the 10 year review period falls during an ongoing compliance review, the review period would be extended until the compliance review is completed.

(f) *Failure to comply.* A QHP issuer that fails to comply with a compliance review under this section may be subject to enforcement remedies under subpart I of this part.

[78 FR 65100, Oct. 30, 2013, as amended at 81 FR 94182, Dec. 22, 2016]

Subpart I—Enforcement Remedies in the Exchanges

SOURCE: 78 FR 54143, Aug. 30, 2013, unless otherwise noted.

§ 156.800 Available remedies; Scope.

(a) *Kinds of sanctions.* HHS may impose the following types of sanctions on QHP issuers in an Exchange that are not in compliance with Exchange standards applicable to issuers offering QHPs in an Exchange:

(1) Civil money penalties as specified in § 156.805; and

(2) Decertification of a QHP offered by the non-compliant QHP issuer in a Federally-facilitated Exchange as described in § 156.810.

(b) *Scope.* Sanctions under subpart I are applicable for non-compliance with QHP issuer participation standards and other standards applicable to issuers offering QHPs in a Federally-facilitated Exchange. Sanctions under paragraph (a)(1) of this section are also applicable for non-compliance by QHP issuers participating in State Exchanges and State-based Exchanges on the Federal platform when HHS is responsible for enforcement of the requirements in subpart E of this part and 45 CFR 156.50.

(c) *Compliance standard.* For calendar years 2014 and 2015, sanctions under this subpart will not be imposed if the QHP issuer has made good faith efforts to comply with applicable requirements.

(d) *Information sharing.* HHS may consult and share information about QHP issuers with other Federal and State regulatory and enforcement entities to the extent that the consultation and information is necessary for purposes of State or Federal oversight and enforcement activities.

[78 FR 54143, Aug. 30, 2013, as amended at 79 FR 30351, May 27, 2014; 80 FR 10875, Feb. 27, 2015; 86 FR 24293, May 5, 2021]

§ 156.805 Bases and process for imposing civil money penalties in Federally-facilitated Exchanges.

(a) *Grounds for imposing civil money penalties.* Civil money penalties may be imposed on an issuer in an Exchange if, based on credible evidence, HHS has reasonably determined that the issuer has engaged in one or more of the following actions:

(1) Misconduct in the Federally-facilitated Exchange or substantial noncompliance with the Exchange standards and requirements applicable to issuers offering QHPs in the Federally-facilitated Exchange, including but not limited to issuer standards and requirements under parts 153 and 156 of this subchapter;

(2) Limiting the QHP's enrollees' access to medically necessary items and services that are required to be covered as a condition of the QHP issuer's ongoing participation in the Federally-facilitated Exchange, if the limitation has adversely affected or has a substantial likelihood of adversely affecting one or more enrollees in the QHP offered by the QHP issuer;

(3) Imposing on enrollees premiums in excess of the monthly beneficiary

premiums permitted by Federal standards applicable to QHP issuers participating in the Federally-facilitated Exchange;

(4) Engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment into a QHP offered by the issuer (except as permitted by this part) by qualified individuals whose medical condition or history indicates the potential for a future need for significant medical services or items;

(5) Intentionally or recklessly misrepresenting or falsifying information that it furnishes—

(i) To HHS or an Exchange; or

(ii) To an individual or entity upon which HHS relies to make its certifications or evaluations of the QHP issuer's ongoing compliance with Exchange standards applicable to issuers offering QHPs in the Federally-facilitated Exchange;

(6) Failure to remit user fees assessed under §156.50(c); or

(7) Failure to comply with the cost-sharing reductions and advance payments of the premium tax credit standards of subpart E of this part.

(b) *Factors in determining the amount of civil money penalties assessed.* In determining the amount of civil money penalties, HHS may take into account the following:

(1) The QHP issuer's previous or ongoing record of compliance;

(2) The level of the violation, as determined in part by—

(i) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread; and

(ii) The magnitude of financial and other impacts on enrollees and qualified individuals; and

(3) Aggravating or mitigating circumstances, or other such factors as justice may require, including complaints about the issuer with regard to the issuer's compliance with the medical loss ratio standards required by the Affordable Care Act and as codified by applicable regulations.

(c) *Maximum penalty.* The maximum amount of penalty imposed for each violation is $100 as adjusted annually under 45 CFR part 102 for each day for each QHP issuer for each individual adversely affected by the QHP issuer's non-compliance; and where the number of individuals cannot be determined, HHS may estimate the number of individuals adversely affected by the violation.

(d) *Request for hearing.* (1) An issuer may appeal the assessment of a civil money penalty under this section by filing a request for hearing under an applicable administrative hearing process.

(2) If an issuer files a request for hearing under this paragraph (d), the assessment of a civil money penalty will not occur prior to the issuance of the final administrative decision in the appeal.

(e) *Failure to request a hearing.* (1) If the QHP issuer does not request a hearing within 30 days of the issuance of the notice described in paragraph (d)(1) of this section, HHS may assess the proposed civil money penalty.

(2) HHS will notify the issuer in writing of any penalty that has been assessed under this subpart and of the means by which the QHP issuer or another responsible entity may satisfy the CMP assessment.

(3) The QHP issuer has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with the requirements of the applicable administrative hearing process unless the QHP issuer can show good cause, as determined under §156.905(b), for failing to timely exercise its right to a hearing.

(f) *Circumstances requiring HHS enforcement in State Exchanges and State-based Exchanges on the Federal platform.* (1) HHS will enforce the requirements of subpart E of this part and 45 CFR 156.50 if a State Exchange or State-based Exchange on the Federal platform notifies HHS that it is not enforcing these requirements or if HHS makes a determination using the process set forth at 45 CFR 150.201, *et seq.* that a State Exchange or State-based Exchange on the Federal platform is failing to substantially enforce these requirements.

(2) If HHS is responsible under paragraph (f)(1) of this section for enforcement of the requirements set forth in subpart E of this part or 45 CFR 156.50,

HHS may impose civil money penalties on an issuer in a State Exchange or State-based Exchange on the Federal platform, in accordance with the bases and process for imposing civil money penalties set forth in this section.

[78 FR 54143, Aug. 30, 2013, as amended at 79 FR 15245, Mar. 19, 2014; 79 FR 30351, May 27, 2014; 81 FR 12351, Mar. 8, 2016; 81 FR 61581, Sept. 6, 2016; 86 FR 24293, May 5, 2021]

§ 156.806 Notice of non-compliance.

If HHS learns of a potential violation described in § 156.805 or if a State informs HHS of a potential violation, prior to imposing any CMPs, HHS must provide a written notice to the issuer, to include the following:

(a) Describe the potential violation.

(b) Provide 30 days from the date of the notice for the QHP issuer to respond and to provide additional information to refute an alleged violation.

(c) State that a civil money penalty may be assessed if the allegations are not, as determined by HHS, refuted.

[79 FR 30351, May 27, 2014]

§ 156.810 Bases and process for decertification of a QHP offered by an issuer through a Federally-facilitated Exchange.

(a) *Bases for decertification.* A QHP may be decertified on one or more of the following grounds:

(1) The QHP issuer substantially fails to comply with the Federal laws and regulations applicable to QHP issuers participating in the Federally-facilitated Exchange;

(2) The QHP issuer substantially fails to comply with the standards related to the risk adjustment, reinsurance, or risk corridors programs under 45 CFR part 153, including providing HHS with valid risk adjustment, reinsurance or risk corridors data;

(3) The QHP issuer substantially fails to comply with the transparency and marketing standards in §§ 156.220 and 156.225;

(4) The QHP issuer substantially fails to comply with the standards regarding advance payments of the premium tax credit and cost-sharing in subpart E of this part;

(5) The QHP issuer is operating in the Federally-facilitated Exchange in a manner that hinders the efficient and effective administration of the Exchange;

(6) The QHP no longer meets the applicable standards set forth under subpart C of this part.

(7) Based on credible evidence, the QHP issuer has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data;

(8) The QHP issuer substantially fails to meet the requirements under § 156.230 related to network adequacy standards or, § 156.235 related to inclusion of essential community providers;

(9) The QHP issuer substantially fails to comply with the law and regulations related to internal claims and appeals and external review processes;

(10) The State recommends to HHS that the QHP should no longer be available in a Federally-facilitated Exchange;

(11) The QHP issuer substantially fails to comply with the privacy or security standards set forth in § 156.260;

(12) The QHP issuer substantially fails to meet the requirements related to the cases forwarded to QHP issuers under subpart K of this part;

(13) The QHP issuer substantially fails to meet the requirements related to the offering of a QHP under subpart M of this part;

(14) The QHP issuer offering the QHP is the subject of a pending, ongoing, or final State regulatory or enforcement action or determination that relates to the issuer offering QHPs in the Federally-facilitated Exchanges; or

(15) HHS reasonably believes that the QHP issuer lacks the financial viability to provide coverage under its QHPs until the end of the plan year.

(b) *State sanctions and determinations*—(1) *State sanctions.* HHS may consider regulatory or enforcement actions taken by a State against a QHP issuer as a factor in determining whether to decertify a QHP offered by that issuer.

(2) *State determinations.* HHS may decertify a QHP offered by an issuer in a Federally-facilitated Exchange based on a determination or action by a State as it relates to the issuer offering QHPs in a Federally-facilitated Exchange, including when a State places an issuer or its parent organization

into receivership or when the State recommends to HHS that the QHP no longer be available in a Federally-facilitated Exchange.

(c) *Standard decertification process.* For decertification actions on grounds other than those described in paragraphs (a)(7), (8), or (9) of this section, HHS will provide written notices to the QHP issuer, enrollees in that QHP, and the State department of insurance in the State in which the QHP is being decertified. The written notice must include the following:

(1) The effective date of the decertification, which will be a date specified by HHS that is no earlier than 30 days after the date of issuance of the notice;

(2) The reason for the decertification, including the regulation or regulations that are the basis for the decertification;

(3) For the written notice to the QHP issuer, information about the effect of the decertification on the ability of the issuer to offer the QHP in the Federally-facilitated Exchange and must include information about the procedure for appealing the decertification by making a hearing request; and

(4) The written notice to the QHP enrollees must include information about the effect of the decertification on enrollment in the QHP and about the availability of a special enrollment period, as described in §155.420 of this subchapter.

(d) *Expedited decertification process.* For decertification actions on grounds described in paragraphs (a)(6), (7), (8), or (9) of this section, HHS will provide written notice to the QHP issuer, enrollees, and the State department of insurance in the State in which the QHP is being decertified. The written notice must include the following:

(1) The effective date of the decertification, which will be a date specified by HHS; and

(2) The information required by paragraphs (c)(2) through (4) of this section.

(e) *Request for hearing.* An issuer may appeal the decertification of a QHP offered by that issuer under paragraph (c) or (d) of this section by filing a request for hearing under an applicable administrative hearing process.

(1) If an issuer files a request for hearing under this paragraph (e):

(i) If the decertification is under paragraph (b)(1) of this section, the decertification will not take effect prior to the issuance of the final administrative decision in the appeal, notwithstanding the effective date specified in paragraph (b)(1) of this section.

(ii) If the decertification is under paragraph (b)(2) of this section, the decertification will be effective on the date specified in the notice of decertification, but the certification of the QHP may be reinstated immediately upon issuance of a final administrative decision that the QHP should not be decertified.

(2) [Reserved]

[78 FR 54143, Aug. 30, 2013, as amended at 79 FR 30351, May 27, 2014; 81 FR 12351, Mar. 8, 2016]

§156.815 Plan suppression.

(a) *Suppression* means temporarily making a QHP certified to be offered through the Federally-facilitated Exchange unavailable for enrollment through the Federally-facilitated Exchange.

(b) *Grounds for suppression.* A QHP may be suppressed as described in paragraph (a) of this section on one or more of the following grounds:

(1) The QHP issuer notifies HHS of its intent to withdraw the QHP from a Federally-facilitated Exchange when one of the exceptions to guaranteed renewability of coverage related to discontinuing a particular product or discontinuing all coverage under §147.106(c) or (d) of this subchapter applies;

(2) Data submitted for the QHP is incomplete or inaccurate;

(3) The QHP is in the process of being decertified as described in §156.810(c) or (d), or the QHP issuer is appealing a completed decertification as described in subpart J of this part;

(4) The QHP issuer offering the QHP is the subject of a pending, ongoing, or final State regulatory or enforcement action or determination that could affect the issuer's ability to enroll consumers or otherwise relates to the issuer offering QHPs in the Federally-facilitated Exchanges; or

(5) One of the exceptions to guaranteed availability of coverage related to

special rules for network plans or financial capacity limits under §147.104(c) or (d) of this subchapter applies.

(c) A multi-State plan as defined in §155.1000(a) of this subchapter may be suppressed as described in paragraph (a) of this section if OPM notifies the Exchange that:

(1) OPM has found a compliance violation within the multi-State plan, or

(2) One of the grounds for suppression in paragraph (b) of this section exists for the multi-State plan.

[80 FR 10875, Feb. 27, 2015]

Subpart J—Administrative Review of QHP Issuer Sanctions

SOURCE: 78 FR 65101, Oct. 30, 2013, unless otherwise noted.

§ 156.901 Definitions.

In this subpart, unless the context indicates otherwise:

ALJ means administrative law judge of the Departmental Appeals Board of HHS.

Filing date means the date filed electronically.

Hearing includes a hearing on a written record as well as an in-person, telephone, or video teleconference hearing.

Party means HHS or the respondent.

Receipt date means five days after the date of a document, unless there is a showing that it was in fact received later.

Respondent means an entity that received a notice of proposed assessment of a civil money penalty issued pursuant to §156.805 or a notice of decertification pursuant to §156.810(c) or (d).

[78 FR 65101, Oct. 30, 2013, as amended at 86 FR 24293, May 5, 2021]

§ 156.903 Scope of Administrative Law Judge's (ALJ) authority.

(a) The ALJ has the authority, including all of the authority conferred by the Administrative Procedure Act (5 U.S.C. 554a), to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a civil money penalty of a QHP offered in a Federally-facilitated Exchange, State Exchange, and State-based Exchange on the Federal platform, or the decertification of a QHP offered in a Federally-facilitated Exchange.

(b) The ALJ's authority includes the authority to modify, consistent with the Administrative Procedures Act (5 U.S.C. 552a), any hearing procedures set out in this subpart.

(c) The ALJ does not have the authority to find invalid or refuse to follow Federal statutes or regulations.

[78 FR 65101, Oct. 30, 2013, as amended at 86 FR 24293, May 5, 2021]

§ 156.905 Filing of request for hearing.

(a) A respondent has a right to a hearing before an ALJ if it files a request for hearing that complies with §156.907(a), within 30 days after the date of issuance of either HHS' notice of proposed assessment under §156.805, notice of decertification of a QHP under §156.810(c) or §156.810(d). The request for hearing should be addressed as instructed in the notice of proposed determination. ''date of issuance'' is five (5) days after the filing date, unless there is a showing that the document was received earlier.

(b) The ALJ may extend the time for filing a request for hearing only if the ALJ finds that the respondent was prevented by events or circumstances beyond its control from filing its request within the time specified above. Any request for an extension of time must be made promptly by written motion.

§ 156.907 Form and content of request for hearing.

(a) The request for hearing must do the following:

(1) Identify any factual or legal bases for the assessment or decertifications with which the respondent disagrees.

(2) Describe with reasonable specificity the basis for the disagreement, including any affirmative facts or legal arguments on which the respondent is relying.

(b) Identify the relevant notice of assessment or decertification by date and attach a copy of the notice.

§ 156.909 Amendment of notice of assessment or decertification request for hearing.

The ALJ may permit CMS to amend its notice of assessment or decertification, or permit the respondent to amend a request for hearing that complies with §156.907(a), if the ALJ finds that no undue prejudice to either party will result.

§ 156.911 Dismissal of request for hearing.

An ALJ will order a request for hearing dismissed if the ALJ determines that:

(a) The request for hearing was not filed within 30 days as specified by §156.905(a) or any extension of time granted by the ALJ pursuant to §156.905(b).

(b) The request for hearing fails to meet the requirements of §156.907.

(c) The entity that filed the request for hearing is not a respondent under §156.901.

(d) The respondent has abandoned its request.

(e) The respondent withdraws its request for hearing.

§ 156.913 Settlement.

HHS has exclusive authority to settle any issue or any case, without the consent of the ALJ at any time before or after the ALJ's decision.

§ 156.915 Intervention.

(a) The ALJ may grant the request of an entity, other than the respondent, to intervene if all of the following occur:

(1) The entity has a significant interest relating to the subject matter of the case.

(2) Disposition of the case will, as a practical matter, likely impair or impede the entity's ability to protect that interest.

(3) The entity's interest is not adequately represented by the existing parties.

(4) The intervention will not unduly delay or prejudice the adjudication of the rights of the existing parties.

(b) A request for intervention must specify the grounds for intervention and the manner in which the entity seeks to participate in the proceedings. Any participation by an intervenor must be in the manner and by any deadline set by the ALJ.

(c) The Department of Labor (DOL) or the Internal Revenue Service (IRS) may intervene without regard to paragraphs (a)(1) through (3) of this section.

§ 156.917 Issues to be heard and decided by ALJ.

(a) The ALJ has the authority to hear and decide the following issues:

(1) Whether a basis exists to assess a civil money penalty against the respondent.

(2) Whether the amount of the assessed civil money penalty is reasonable.

(3) Whether a basis exists to decertify a QHP offered by the respondent in a Federally-facilitated Exchange.

(b) In deciding whether the amount of a civil money penalty is reasonable, the ALJ—

(1) Will apply the factors that are identified in §156.805 for civil money penalties.

(2) May consider evidence of record relating to any factor that HHS did not apply in making its initial determination, so long as that factor is identified in this subpart.

(c) If the ALJ finds that a basis exists to assess a civil money penalty, the ALJ may sustain, reduce, or increase the penalty that HHS assessed.

§ 156.919 Forms of hearing.

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, by telephone, or by video teleconference. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness' direct testimony in writing only if the witness is available for cross-examination.

(b) The ALJ may decide a case based solely on the written record where there is no disputed issue of material fact the resolution of which requires the receipt of oral testimony.

[78 FR 65101, Oct. 30, 2013, as amended at 86 FR 24293, May 5, 2021]

§ 156.921 Appearance of counsel.

Any attorney who is to appear on behalf of a party must promptly file, with the ALJ, a notice of appearance.

§ 156.923 Communications with the ALJ.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 156.925 Motions.

(a) Any request to the ALJ for an order or ruling must be by motion, stating the relief sought, the authority relied upon, and the facts alleged. All motions must be in writing, with a copy served on the opposing party, except in either of the following situations:

(1) The motion is presented during an oral proceeding before an ALJ at which both parties have the opportunity to be present.

(2) An extension of time is being requested by agreement of the parties or with waiver of objections by the opposing party.

(b) Unless otherwise specified in this subpart, any response or opposition to a motion must be filed within 20 days of the party's receipt of the motion. The ALJ does not rule on a motion before the time for filing a response to the motion has expired except where the response is filed at an earlier date, where the opposing party consents to the motion being granted, or where the ALJ determines that the motion should be denied.

§ 156.927 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed electronically and include:

(1) A caption on the first page, setting forth the title of the case, the docket number (if known), and a description of the submission (such as ''Motion for Discovery'').

(2) The signatory's name, address, and telephone number.

(3) A signed certificate of service, specifying each address to which a copy of the submission is sent, the date on which it is sent, and the method of service.

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. If a party is represented by an attorney, service must be made on the attorney. An electronically filed submission is considered served on all parties using the electronic filing system.

[78 FR 65101, Oct. 30, 2013, as amended at 86 FR 24293, May 5, 2021]

§ 156.929 Computation of time and extensions of time.

(a) For purposes of this subpart, in computing any period of time, the time begins with the day following the act, event, or default and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal government, in which event it includes the next business day. When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government are excluded from the computation.

(b) The period of time for filing any responsive pleading or papers is determined by the date of receipt (as defined in §156.901) of the submission to which a response is being made.

(c) The ALJ may grant extensions of the filing deadlines specified in these regulations or set by the ALJ for good cause shown (except that requests for extensions of time to file a request for hearing may be granted only on the grounds specified in §156.905(b)).

§ 156.931 Acknowledgement of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a written notice to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case,

and provides instructions for filing submissions and other general information concerning procedures. The ALJ will set out the next steps in the case either as part of the acknowledgement or on a later date.

[86 FR 24293, May 5, 2021]

§ 156.935 Discovery.

(a) The parties must identify any need for discovery from the opposing party as soon as possible, but no later than the time for the reply specified in § 156.937(c). Upon request of a party, the ALJ may stay proceedings for a reasonable period pending completion of discovery if the ALJ determines that a party would not be able to make the submissions required by § 156.937 without discovery. The parties should attempt to resolve any discovery issues informally before seeking an order from the ALJ.

(b) Discovery devices may include requests for production of documents, requests for admission, interrogatories, depositions, and stipulations. The ALJ orders interrogatories or depositions only if these are the only means to develop the record adequately on an issue that the ALJ must resolve to decide the case.

(c) Each discovery request must be responded to within 30 days of receipt, unless that period of time is extended for good cause by the ALJ.

(d) A party to whom a discovery request is directed may object in writing for any of the following reasons:

(1) Compliance with the request is unduly burdensome or expensive.

(2) Compliance with the request will unduly delay the proceedings.

(3) The request seeks information that is wholly outside of any matter in dispute.

(4) The request seeks privileged information. Any party asserting a claim of privilege must sufficiently describe the information or document being withheld to show that the privilege applies. If an asserted privilege applies to only part of a document, a party withholding the entire document must state why the nonprivileged part is not segregable.

(5) The disclosure of information responsive to the discovery request is prohibited by law.

(e) Any motion to compel discovery must be filed within 10 days after receipt of objections to the party's discovery request, within 10 days after the time for response to the discovery request has elapsed if no response is received, or within 10 days after receipt of an incomplete response to the discovery request. The motion must be reasonably specific as to the information or document sought and must state its relevance to the issues in the case.

§ 156.937 Submission of briefs and proposed hearing exhibits.

(a) Within 60 days of its receipt of the acknowledgment provided for in § 156.931, the respondent must file the following with the ALJ:

(1) A statement of its arguments concerning CMS's notice of assessment or decertification (respondent's brief), including citations to the respondent's hearing exhibits provided in accordance with paragraph (a)(2) of this section. The brief may not address factual or legal bases for the assessment or decertification that the respondent did not identify as disputed in its request for hearing or in an amendment to that request permitted by the ALJ.

(2) All documents (including any affidavits) supporting its arguments, tabbed and organized chronologically and accompanied by an indexed list identifying each document.

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any stipulations or admissions.

(b) Within 30 days of its receipt of the respondent's submission required by paragraph (a) of this section, CMS will file the following with the ALJ:

(1) A statement responding to the respondent's brief, including the respondent's proposed hearing exhibits, if appropriate. The statement may include citations to CMS's proposed hearing exhibits submitted in accordance with paragraph (b)(2) of this section.

(2) Any documents supporting CMS's response not already submitted as part of the respondent's proposed hearing

exhibits, organized and indexed as indicated in paragraph (a)(2) of this section (CMS's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any admissions or stipulations.

(c) Within 15 days of its receipt of CMS's submission required by paragraph (b) of this section, the respondent may file with the ALJ a reply to CMS's submission.

§ 156.939 Effect of submission of proposed hearing exhibits.

(a) Any proposed hearing exhibit submitted by a party in accordance with § 156.937 is deemed part of the record unless the opposing party raises an objection to that exhibit and the ALJ rules to exclude it from the record. An objection must be raised either in writing prior to the prehearing conference provided for in § 156.941 or at the prehearing conference. The ALJ may require a party to submit the original hearing exhibit on his or her own motion or in response to a challenge to the authenticity of a proposed hearing exhibit.

(b) A party may introduce a proposed hearing exhibit following the times for submission specified in § 156.937 only if the party establishes to the satisfaction of the ALJ that it could not have produced the exhibit earlier and that the opposing party will not be prejudiced.

§ 156.941 Prehearing conferences.

An ALJ may schedule one or more prehearing conferences (generally conducted by telephone) on the ALJ's own motion or at the request of either party for the purpose of any of the following:

(a) Hearing argument on any outstanding discovery request.

(b) Establishing a schedule for any supplements to the submissions required by § 156.937 because of information obtained through discovery.

(c) Hearing argument on a motion.

(d) Discussing whether the parties can agree to submission of the case on a stipulated record.

(e) Establishing a schedule for an in-person, telephone, or video teleconference hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

(f) Discussing whether the issues for a hearing can be simplified or narrowed.

(g) Discussing potential settlement of the case.

(h) Discussing any other procedural or substantive issues.

[78 FR 65101, Oct. 30, 2013, as amended at 86 FR 24293, May 5, 2021]

§ 156.943 Standard of proof.

(a) In all cases before an ALJ—

(1) CMS has the burden of coming forward with evidence sufficient to establish a prima facie case;

(2) The respondent has the burden of coming forward with evidence in response, once CMS has established a prima facie case; and

(3) CMS has the burden of persuasion regarding facts material to the assessment or decertification; and

(4) The respondent has the burden of persuasion regarding facts relating to an affirmative defense.

(b) The preponderance of the evidence standard applies to all cases before the ALJ.

§ 156.945 Evidence.

(a) The ALJ will determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ will not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate; for example, to exclude unreliable evidence.

(c) The ALJ excludes irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence is excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement made in this action will be inadmissible to the extent

provided in the Federal Rules of Evidence.

(g) Evidence of acts other than those at issue in the instant case is admissible in determining the amount of any civil money penalty if those acts are used under §156.805 of this part to consider the entity's prior record of compliance, or to show motive, opportunity, intent, knowledge, preparation, identity, or lack of mistake. This evidence is admissible regardless of whether the acts occurred during the statute of limitations period applicable to the acts that constitute the basis for liability in the case and regardless of whether HHS' notice sent in accordance with §156.805 referred to them.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless the ALJ orders otherwise for good cause shown.

(j) The ALJ may not consider evidence regarding the willingness and ability to enter into and successfully complete a corrective action plan when that evidence pertains to matters occurring after HHS' notice under §156.805(d) or §156.810(c) or §156.810(d).

§156.947 The record.

(a) Any testimony that is taken in-person, by telephone, or by video teleconference is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

(b) The transcript of any testimony, exhibits and other evidence that is admitted, and all pleadings and other documents that are filed in the case constitute the record for purposes of an ALJ decision.

(c) For good cause, the ALJ may order appropriate redactions made to the record.

[78 FR 65101, Oct. 30, 2013, as amended at 86 FR 24293, May 5, 2021]

§156.951 Posthearing briefs.

Each party is entitled to file proposed findings and conclusions, and supporting reasons, in a posthearing brief. The ALJ will establish the schedule by which such briefs must be filed. The ALJ may direct the parties to brief specific questions in a case and may impose page limits on posthearing briefs. Additionally, the ALJ may allow the parties to file posthearing reply briefs.

§156.953 ALJ decision.

The ALJ will issue an initial agency decision based only on the record and on applicable law; the decision will contain findings of fact and conclusions of law. The ALJ's decision is final and appealable after 30 days unless it is modified or vacated under §156.957.

§156.955 Sanctions.

(a) The ALJ may sanction a party or an attorney for failing to comply with an order or other directive or with a requirement of a regulation, for abandonment of a case, or for other actions that interfere with the speedy, orderly or fair conduct of the hearing. Any sanction that is imposed will relate reasonably to the severity and nature of the failure or action.

(b) A sanction may include any of the following actions:

(1) In the case of failure or refusal to provide or permit discovery, drawing negative fact inferences or treating such failure or refusal as an admission by deeming the matter, or certain facts, to be established.

(2) Prohibiting a party from introducing certain evidence or otherwise advocating a particular claim or defense.

(3) Striking pleadings, in whole or in part.

(4) Staying the case.

(5) Dismissing the case.

(6) Entering a decision by default.

(7) Refusing to consider any motion or other document that is not filed in a timely manner.

(8) Taking other appropriate action.

§156.957 Review by Administrator.

(a) The Administrator of CMS (which for purposes of this section may include his or her delegate), at his or her discretion, may review in whole or in part any initial agency decision issued under §156.953.

(b) The Administrator may decide to review an initial agency decision if it

appears from a preliminary review of the decision (or from a preliminary review of the record on which the initial agency decision was based, if available at the time) that:

(1) The ALJ made an erroneous interpretation of law or regulation.

(2) The initial agency decision is not supported by substantial evidence.

(3) The ALJ has incorrectly assumed or denied jurisdiction or extended his or her authority to a degree not provided for by statute or regulation.

(4) The ALJ decision requires clarification, amplification, or an alternative legal basis for the decision.

(5) The ALJ decision otherwise requires modification, reversal, or remand.

(c) Within 30 days of the date of the initial agency decision, the Administrator will mail a notice advising the respondent of any intent to review the decision in whole or in part.

(d) Within 30 days of receipt of a notice that the Administrator intends to review an initial agency decision, the respondent may submit, in writing, to the Administrator any arguments in support of, or exceptions to, the initial agency decision.

(e) This submission of the information indicated in paragraph (d) of this section must be limited to issues the Administrator has identified in his or her notice of intent to review, if the Administrator has given notice of an intent to review the initial agency decision only in part. A copy of this submission must be sent to the other party.

(f) After receipt of any submissions made pursuant to paragraph (d) of this section and any additional submissions for which the Administrator may provide, the Administrator will affirm, reverse, modify, or remand the initial agency decision. The Administrator will mail a copy of his or her decision to the respondent.

(g) The Administrator's decision will be based on the record on which the initial agency decision was based (as forwarded by the ALJ to the Administrator) and any materials submitted pursuant to paragraphs (b), (d), and (f) of this section.

(h) The Administrator's decision may rely on decisions of any courts and other applicable law, whether or not cited in the initial agency decision.

§ 156.959 Judicial review.

(a) *Filing of an action for review.* Any responsible entity against whom a final order imposing a civil money penalty or decertification of a QHP is entered may obtain review in the United States District Court for any district in which the entity is located or in the United States District Court for the District of Columbia by doing the following:

(1) Filing a notice of appeal in that court within 30 days from the date of a final order.

(2) Simultaneously sending a copy of the notice of appeal by registered mail to HHS.

(b) *Certification of administrative record.* HHS promptly certifies and files with the court the record upon which the penalty was assessed.

(c) *Standard of review.* The findings of HHS and the ALJ may not be set aside unless they are found to be unsupported by substantial evidence, as provided by 5 U.S.C. 706(2)(E).

§ 156.961 Failure to pay assessment.

If any entity fails to pay an assessment after it becomes a final order, or after the court has entered final judgment in favor of CMS, CMS refers the matter to the Attorney General, who brings an action against the entity in the appropriate United States district court to recover the amount assessed.

§ 156.963 Final order not subject to review.

In an action brought under § 156.961, the validity and appropriateness of the final order imposing a civil money penalty is not subject to review.

Subpart K—Cases Forwarded to Qualified Health Plans and Qualified Health Plan Issuers in Federally-facilitated Exchanges

SOURCE: 78 FR 54143, Aug. 30, 2013, unless otherwise noted.

§ 156.1010 Standards.

(a) A case is a communication brought by a complainant that expresses dissatisfaction with a specific person or entity subject to State or Federal laws regulating insurance, concerning the person or entity's activities related to the offering of insurance, other than a communication with respect to an adverse benefit determination as defined in §147.136(a)(2)(i) of this subchapter. Issues related to adverse benefit determinations are not addressed in this section and are subject to the provisions in §147.136 of this subchapter governing internal claims appeals and external review. Issues related to eligibility determination processes and appeals are not addressed in this section and are subject to the provisions in subpart F of part 155.

(b) QHP issuers operating in a Federally-facilitated Exchange must investigate and resolve, as appropriate, cases from the complainant forwarded to the issuer by HHS. Cases received by a QHP issuer operating in a Federally-facilitated Exchange directly from a complainant or the complainant's authorized representative will be handled by the issuer through its internal customer service process.

(c) Cases may be forwarded to a QHP issuer operating in a Federally-facilitated Exchange through a casework tracking system developed by HHS or other means as determined by HHS.

(d) Cases received by a QHP issuer operating in a Federally-facilitated Exchange from HHS must be resolved within 15 calendar days of receipt of the case. Urgent cases as defined in paragraph (e) of this section that do not otherwise fall within the scope of §147.136 of this subchapter must be resolved no later than 72 hours after receipt of the case. Where applicable State laws and regulations establish timeframes for case resolution that are stricter than the standards contained in this paragraph, QHP issuers operating in a Federally-facilitated Exchange must comply with such stricter laws and regulations.

(e) For cases received from HHS by a QHP issuer operating in a Federally-facilitated Exchange, an urgent case is one in which there is an immediate need for health services because the non-urgent standard could seriously jeopardize the enrollee's or potential enrollee's life, or health or ability to attain, maintain, or regain maximum function; or one in which the process for non-urgent cases would jeopardize the enrollee's or potential enrollee's ability enroll in a QHP through the Federally-facilitated Exchange.

(f) For cases received from HHS, QHP issuers operating in a Federally-facilitated Exchange are required to notify complainants regarding the disposition of the as soon as possible upon resolution of the case, but in no event later than three (3) business days after the case is resolved.

(1) For the purposes of meeting the requirement in this paragraph (f), notification may be by verbal or written means as determined most appropriate by the QHP issuer.

(2) In instances when the initial notification of a case's disposition is not written, written notification must be provided to the consumer in a timely manner.

(g) For cases received from HHS, QHP issuers operating in a Federally-facilitated Exchange must use the casework tracking system developed by HHS, or other means as determined by HHS, to document the following:

(1) The date of resolution of a case received from HHS;

(2) A resolution summary of the case no later than seven (7) business days after resolution of the case. The record must include a clear and concise narrative explaining how the case was resolved including information about how and when the complainant was notified of the resolution; and

(3) For a case in which a State agency, including but not limited to a State department of insurance, conducts an investigation related to that case, any compliance issues identified by the State agency implicating the QHP or QHP issuer.

(h) Cases received by a QHP issuer operating in a Federally-facilitated Exchange from a State in which the issuer offers QHPs must be investigated and resolved according to applicable State laws and regulations. With respect to cases directly handled by the State, HHS or any other appropriate regulatory authority, QHP

issuers operating in a Federally-facilitated Exchange must cooperate fully with the efforts of the State, HHS, or other regulatory authority to resolve the case.

Subpart L—Quality Standards

SOURCE: 78 FR 65105, Oct. 30, 2013, unless otherwise noted.

§ 156.1105 Establishment of standards for HHS-approved enrollee satisfaction survey vendors for use by QHP issuers in Exchanges.

(a) *Application for approval.* An enrollee satisfaction survey vendor must be approved by HHS, in a form and manner to be determined by HHS, to administer, on behalf of a QHP issuer, enrollee satisfaction surveys to QHP enrollees. HHS will approve enrollee satisfaction survey vendors on an annual basis, and each enrollee satisfaction survey vendor must submit an application for each year that approval is sought.

(b) *Standards.* To be approved by HHS, an enrollee satisfaction survey vendor must meet each of the following standards:

(1) Sign and submit an application form for approval in accordance with paragraph (a) of this section;

(2) Ensure, on an annual basis, that appropriate staff participate in enrollee satisfaction survey vendor training and successfully complete a post-training certification exercise as established by HHS;

(3) Ensure the accuracy of their data collection, calculation and submission processes and attest to HHS the veracity of the data and these processes;

(4) Sign and execute a standard HHS data use agreement, in a form and manner to be determined by HHS, that establishes protocols related to the disclosure, use, and reuse of HHS data;

(5) Adhere to the enrollee satisfaction survey protocols and technical specifications in a manner and form required by HHS;

(6) Develop and submit to HHS a quality assurance plan and any supporting documentation as determined to be relevant by HHS. The plan must describe in adequate detail the implementation of and compliance with all required protocols and technical specifications described in paragraph (b)(5) of this section;

(7) Adhere to privacy and security standards established and implemented under §155.260 of this subchapter by the Exchange with which they are associated;

(8) Comply with all applicable State and Federal laws;

(9) Become a registered user of the enrollee satisfaction survey data warehouse to submit files to HHS on behalf of its authorized QHP contracts;

(10) Participate in and cooperate with HHS oversight for quality-related activities, including, but not limited to: review of the enrollee satisfaction survey vendor's quality assurance plan and other supporting documentation; analysis of the vendor's submitted data and sampling procedures; and site visits and conference calls; and,

(11) Comply with minimum business criteria as established by HHS.

(c) *Approved list.* A list of approved enrollee satisfaction survey vendors will be published on an HHS Web site.

(d) *Monitoring.* HHS will periodically monitor HHS-approved enrollee satisfaction survey vendors to ensure ongoing compliance with the standards in paragraph (b) of this section. If HHS determines that an HHS-approved enrollee satisfaction survey vendor is non-compliant with the standards required in paragraph (b) of this section, the survey vendor may be removed from the approved list described in paragraph (c) of this section and/or the submitted survey results may be ineligible to be included for ESS results.

(e) *Appeals.* An enrollee satisfaction survey vendor that is not approved by HHS after submitting the application described in paragraph (a) of this section may appeal HHS's decision by notifying HHS in writing within 15 days from receipt of the notification of not being approved and submitting additional documentation demonstrating how the vendor meets the standards in paragraph (b) of this section. HHS will review the submitted documentation and make a final approval determination within 30 days from receipt of the additional documentation.

[78 FR 65105, Oct. 30, 2013, as amended at 79 FR 30351, May 27, 2014]

§ 156.1110 Establishment of patient safety standards for QHP issuers.

(a) *Patient safety standards.* A QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital, as defined in section 1861(e) of the Act:

(1) For plan years beginning before January 1, 2017, is Medicare-certified or has been issued a Medicaid-only CMS Certification Number (CCN) and is subject to the Medicare Hospital Conditions of Participation requirements for—

(i) A quality assessment and performance improvement program as specified in 42 CFR 482.21; and

(ii) Discharge planning as specified in 42 CFR 482.43.

(2) For plan years beginning on or after January 1, 2017—

(i)(A) Utilizes a patient safety evaluation system as defined in 42 CFR 3.20; and

(B) Implements a mechanism for comprehensive person-centered hospital discharge to improve care coordination and health care quality for each patient; or

(ii) Implements an evidence-based initiative, to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination.

(3) A QHP issuer must ensure that each of its QHPs meets the patient safety standards in accordance with this section.

(b) *Documentation.* A QHP issuer must collect:

(1) For plan years beginning before January 1, 2017, the CCN from each of its contracted hospitals with greater than 50 beds, to demonstrate that those hospitals meet patient safety standards required in paragraph (a)(1) of this section; and

(2) For plan years beginning on or after January 1, 2017, information, from each of its contracted hospitals with greater than 50 beds, to demonstrate that those hospitals meet patient safety standards required in paragraph (a)(2) of this section.

(c) *Reporting.* (1) A QHP issuer must make available to the Exchange the documentation referenced in paragraph (b) of this section, upon request by the Exchange, in a time and manner specified by the Exchange.

(2) Issuers of multi-State plans, as defined in §155.1000(a) of this subchapter, must provide the documentation described in paragraph (b) of this section to the U.S. Office of Personnel Management, in the time and manner specified by the U.S. Office of Personnel Management.

[79 FR 13841, Mar. 11, 2014, as amended at 81 FR 12351, Mar. 8, 2016]

§ 156.1120 Quality rating system.

(a) *Data submission requirement.* (1) A QHP issuer must submit data to HHS and Exchanges to support the calculation of quality ratings for each QHP that has been offered in an Exchange for at least one year.

(2) In order to ensure the integrity of the data required to calculate the QRS, a QHP issuer must submit data that has been validated in a form and manner specified by HHS.

(3) A QHP issuer must include in its data submission information only for those QHP enrollees at the level specified by HHS.

(b) *Timeline.* A QHP issuer must annually submit data necessary to calculate the QHP's quality ratings to HHS and Exchanges, on a timeline and in a standardized form and manner specified by HHS.

(c) *Marketing requirement.* A QHP issuer may reference the quality ratings for its QHPs in its marketing materials, in a manner specified by HHS.

(d) *Multi-State plans.* Issuers of multi-State plans, as defined in §155.1000(a) of this subchapter, must provide the data described in paragraph (a) of this section to the U.S. Office of Personnel Management, in the time and manner specified by the U.S. Office of Personnel Management.

[79 FR 30352, May 27, 2014]

§ 156.1125 Enrollee satisfaction survey system.

(a) *General requirement.* A QHP issuer must contract with an HHS-approved enrollee satisfaction survey (ESS) vendor, as identified by §156.1105, in order to administer the Enrollee Satisfaction Survey of the QHP's enrollees. A QHP

issuer must authorize its contracted ESS vendor to report survey results to HHS and the Exchange on the issuer's behalf.

(b) *Data requirement.* (1) A QHP issuer must collect data for each QHP, with more than 500 enrollees in the previous year that has been offered in an Exchange for at least one year and following a survey sampling methodology provided by HHS.

(2) In order to ensure the integrity of the data required to conduct the survey, a QHP issuer must submit data that has been validated in a form and manner specified by HHS, and submit this data to its contracted ESS vendor.

(3) A QHP issuer must include in its data submission information only for those QHP enrollees at the level specified by HHS.

(c) *Marketing requirement.* A QHP issuer may reference the survey results for its QHPs in its marketing materials, in a manner specified by HHS.

(d) *Timeline.* A QHP issuer must annually submit data necessary to conduct the survey to its contracted ESS vendor on a timeline and in a standardized form and manner specified by HHS.

(e) *Multi-State plans.* Issuers of multi-State plans, as defined in §155.1000(a) of this subchapter, must provide the data described in paragraph (b) of this section to the U.S. Office of Personnel Management, in the time and manner specified by the U.S. Office of Personnel Management.

[79 FR 30352, May 27, 2014]

§156.1130 Quality improvement strategy.

(a) *General requirement.* A QHP issuer participating in an Exchange for 2 or more consecutive years must implement and report on a quality improvement strategy including a payment structure that provides increased reimbursement or other market-based incentives in accordance with the health care topic areas in section 1311(g)(1) of the Affordable Care Act, for each QHP offered in an Exchange, consistent with the guidelines developed by HHS under section 1311(g) of the Affordable Care Act.

(b) *Data requirement.* A QHP issuer must submit data that has been validated in a manner and timeframe specified by the Exchange to support the evaluation of quality improvement strategies in accordance with §155.200(d) of this subchapter.

(c) *Timeline.* A QHP issuer must submit data annually to evaluate compliance with the standards for a quality improvement strategy in accordance with paragraph (a) of this section, in a manner and timeframe specified by the Exchange.

(d) *Multi-State plans.* Issuers of multi-State plans, as defined in §155.1000(a) of this subchapter, must provide the data described in paragraph (b) of this section to the U.S. Office of Personnel Management, in the manner and timeframe specified by the U.S. Office of Personnel Management.

[80 FR 10876, Feb. 27, 2015]

Subpart M—Qualified Health Plan Issuer Responsibilities

SOURCE: 78 FR 54143, Aug. 30, 2013, unless otherwise noted.

§156.1210 Dispute submission.

(a) *Responses to reports.* Within 90 calendar days of the date of a payment and collections report from HHS, the issuer must, in a form and manner specified by HHS or the State Exchange describe to HHS or the State Exchange (as applicable) any inaccuracies it identifies in the report.

(b) *Inaccuracies identified after 90-day period.* With respect to an inaccuracy described under paragraph (a) of this section that is identified and submitted to HHS or the State Exchange (as applicable) by the issuer after the end of the 90-day period described in such paragraph, HHS will consider and work with the issuer or the State Exchange (as applicable) to resolve the inaccuracy so long as—

(1) The issuer promptly notifies HHS or the State Exchange (as applicable) upon identifying the inaccuracy, but in no case later than 15 calendar days after identifying the inaccuracy; and

(2) The failure to identify the inaccuracy and submit it to HHS or the State Exchange (as applicable) in a timely manner was not unreasonable or due to the issuer's misconduct or negligence.

(c) *Deadline for describing inaccuracies.* To be eligible for resolution under paragraph (b) of this section, an issuer must describe all inaccuracies identified in a payment and collections report before the end of the 3-year period beginning at the end of the plan year to which the inaccuracy relates. For plan years 2015 through 2019, to be eligible for resolution under paragraph (b) of this section, an issuer must describe all inaccuracies identified in a payment and collections report before January 1, 2024. If a payment error is discovered after the timeframe set forth in this paragraph (c), the issuer must notify HHS, the State Exchange, or State-based Exchanges on the Federal platform (SBE–FP) (as applicable) and repay any overpayments to HHS.

(d) *Confirmation of HHS payment and collections reports.* At the end of each payment year, the issuer must, in a form and manner specified by HHS, confirm to HHS that the amounts identified in the most recent payment and collections report for the coverage year accurately reflect applicable payments owed by the issuer to the Federal Government and the payments owed to the issuer by the Federal Government, or that the issuer has disputed any identified inaccuracies.

[85 FR 29262, May 14, 2020, as amended at 86 FR 24294, May 5, 2021; 88 FR 25923, Apr. 27, 2023]

§ 156.1215 Payment and collections processes.

(a) *Netting of payments and charges for 2014.* In 2014, as part of its monthly payment and collections process, HHS will net payments owed to QHP issuers and their affiliates under the same taxpayer identification number against amounts due to the Federal government from the QHP issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of cost-sharing reductions, and payment of Federally-facilitated Exchange user fees.

(b) *Netting of payments and charges for later years.* As part of its payment and collections process, HHS may net payments owed to issuers and their affiliates operating under the same tax identification number against amounts due to the Federal Government from the issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, payment of federally facilitated Exchange user fees, payment of State Exchanges utilizing the Federal platform user fees, HHS risk adjustment, reinsurance, and risk corridors payments and charges, and administrative fees for utilizing the Federal Independent Dispute Resolution process in accordance with §149.510(d)(2) of this subchapter.

(c) *Determination of debt.* Any amount owed to the Federal Government by an issuer and its affiliates for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, Federally-facilitated Exchange user fees, including any fees for State-based Exchanges utilizing the Federal platform, HHS risk adjustment, reinsurance, risk corridors, and unpaid administrative fees for utilizing the Federal Independent Dispute Resolution process in accordance with §149.510(d)(2), after HHS nets amounts owed by the Federal Government under these programs, is a determination of a debt.

[79 FR 13841, Mar. 11, 2014, as amended at 81 FR 12351, Mar. 8, 2016; 86 FR 24294, May 5, 2021; 89 FR 26426, Apr. 15, 2024]

§ 156.1220 Administrative appeals.

(a) *Requests for reconsideration*—(1) *Matters for reconsideration.* An issuer may file a request for reconsideration under this section to contest a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error only with respect to the following:

(i) The amount of advance payment of the premium tax credit, advance payment of cost-sharing reductions or Federally-facilitated Exchange user fees charge for a benefit year;

(ii) The amount of a risk adjustment payment or charge for a benefit year, including an assessment of risk adjustment user fees;

(iii) The amount of a reinsurance payment for a benefit year;

(iv) The amount of a risk adjustment default charge for a benefit year;

(v) The amount of a reconciliation payment or charge for cost-sharing reductions for a benefit year;

(vi) The amount of a risk corridors payment or charge for a benefit year;

(vii) The findings of a second validation audit as a result of risk adjustment data validation (if applicable) with respect to risk adjustment data for the 2016 benefit year and beyond; or

(viii) The calculation of a risk score error rate as a result of risk adjustment data validation with respect to risk adjustment data for the 2016 benefit year and beyond.

(2) *Materiality threshold.* Notwithstanding paragraph (a)(1) of this section, an issuer may file a request for reconsideration under this section only if the amount in dispute under paragraph (a)(1)(i) through (viii) of this section, as applicable, is equal to or exceeds 1 percent of the applicable payment or charge listed in such paragraphs (a)(1)(i) through (viii) of this section payable to or due from the issuer for the benefit year, or $10,000, whichever is less.

(3) *Time for filing a request for reconsideration.* The request for reconsideration must be filed in accordance with the following timeframes:

(i) For advance payments of the premium tax credit, advance payments of cost-sharing reductions, Federally-facilitated Exchange user fee charges, or State-based Exchanges utilizing the Federal platform fees, within 60 calendar days after the date of the final reconsideration notification specifying the aggregate amount of advance payments of the premium tax credit, advance payments of cost-sharing reductions, Federally-facilitated Exchange user fees, and State-based Exchanges utilizing the Federal platform fees for the applicable benefit year;

(ii) For a risk adjustment payment or charge, including an assessment of risk adjustment user fees, within 30 calendar days of the date of the notification under §153.310(e) of this subchapter;

(iii) For the findings of a second validation audit (if applicable), or the calculation of a risk score error rate as a result of risk adjustment data validation, within 30 calendar days of publication of the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers;

(iv) For a reinsurance payment, within 30 calendar days of the date of the notification under §153.240(b)(1)(ii) of this subchapter;

(v) For a default risk adjustment charge, within 30 calendar days of the date of the notification of the default risk adjustment charge;

(vi) For reconciliation of the cost-sharing reduction portion of advance payments, within 60 calendar days of the date of the cost-sharing reduction reconciliation discrepancy resolution decision; and

(vii) For a risk corridors payment or charge, within 30 calendar days of the date of the notification under §153.510(d) of this subchapter.

(4) *Content of request.* (i) The request for reconsideration must specify the findings or issues specified in paragraph (a)(1) of this section that the issuer challenges, and the reasons for the challenge.

(ii) Notwithstanding paragraph (a)(1) of this section, a reconsideration with respect to a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error may be requested only if, to the extent the issue could have been previously identified, the issuer notified HHS of the dispute through the applicable process for reporting a discrepancy set forth in §§153.630(d)(2) and (3) and 153.710(d)(2) of this subchapter and §156.430(h)(1), it was so identified and remains unresolved.

(iii) Notwithstanding paragraph (a)(1) of this section, a reconsideration with respect to advance payments of the premium tax credit, advance payments of cost-sharing reductions, and Federally-facilitated Exchange user fees may be requested only if, to extent the issue could have been previously identified by the issuer to HHS under §156.1210, it was so identified and remains unresolved. An issuer may request reconsideration if it previously identified an issue under §156.1210 after the 15-calendar-day deadline, but late discovery of the issue was not due to misconduct on the part of the issuer.

(iv) The issuer may include in the request for reconsideration additional

documentary evidence that HHS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(5) *Scope of review for reconsideration.* In conducting the reconsideration, HHS will review the appropriate payment and charge determinations, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the issuer. HHS may also review any other evidence it believes to be relevant in deciding the reconsideration, which will be provided to the issuer with a reasonable opportunity to review and rebut the evidence. The issuer must prove its case by a preponderance of the evidence with respect to issues of fact.

(6) *Reconsideration decision.* HHS will inform the issuer of the reconsideration decision in writing. A reconsideration decision is final and binding for decisions regarding the advance payments of the premium tax credit, advance payment of cost-sharing reductions, or Federally-facilitated Exchange user fees. A reconsideration decision with respect to other matters is subject to the outcome of a request for informal hearing filed in accordance with paragraph (b) of this section.

(b) *Informal hearing.* An issuer may request an informal hearing before a CMS hearing officer to appeal HHS's reconsideration decision.

(1) *Manner and timing for request.* A request for an informal hearing must be made in writing and filed with HHS within 30 calendar days of the date of the reconsideration decision under paragraph (a)(5) of this section. If the last day of this period is not a business day, the request for an informal hearing must be made in writing and filed by the next applicable business day.

(2) *Content of request.* The request for informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision that the issuer challenges, and its reasons for the challenge. HHS may submit for review by the CMS hearing officer a statement of its reasons for the reconsideration decision.

(3) *Informal hearing procedures.* (i) The issuer will receive a written notice of the time and place of the informal hearing at least 15 calendar days before the scheduled date.

(ii) The CMS hearing officer will neither receive testimony nor accept any new evidence that was not presented with the reconsideration request and HHS statement under paragraph (b) of this section. The CMS hearing officer will review only the documentary evidence provided by the issuer and HHS, and the record that was before HHS when HHS made its reconsideration determination. The issuer may be represented by counsel in the informal hearing, and must prove its case by clear and convincing evidence with respect to issues of fact.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer will send the informal hearing decision and the reasons for the decision to the issuer. The decision of the CMS hearing officer is final and binding, but is subject to the results of any Administrator's review initiated in accordance with paragraph (c) of this section.

(c) *Review by the Administrator of CMS.* (1) Either the issuer or CMS may request review by the Administrator of CMS of the CMS hearing officer's decision. A request for review of the CMS hearing officer's decision must be submitted to the Administrator of CMS within 15 calendar days of the date of the CMS hearing officer's decision, and must specify the findings or issues that the issuer or CMS challenges. The issuer or CMS may submit for review by the Administrator of CMS a statement supporting the decision of the CMS hearing officer.

(2) After receiving a request for review, the Administrator of CMS has the discretion to elect to review the CMS hearing officer's decision or to decline to review the CMS hearing officer's decision. If the Administrator of CMS elects to review the CMS hearing officer's decision, the Administrator of CMS will also review the statements of the issuer and CMS, and any other information included in the record of the CMS hearing officer's decision, and will determine whether to uphold, reverse, or modify the CMS hearing officer's decision. The issuer or CMS must prove

its case by clear and convincing evidence for issues of fact. The Administrator of CMS will send the decision and the reasons for the decision to the issuer.

(3) The Administrator of CMS's determination is final and binding.

[79 FR 13841, Mar. 11, 2014, as amended at 80 FR 10876, Feb. 27, 2015; 81 FR 12352, Mar. 8, 2016; 81 FR 94182, Dec. 22, 2016; 86 FR 24294, May 5, 2021; 88 FR 25923, Apr. 27, 2023]

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

(a) A QHP issuer that is directly contacted by a potential applicant may, at the Exchange's option, enroll such applicant in a QHP in a manner that is considered through the Exchange. In order for the enrollment to be made directly with the issuer in a manner that is considered to be through the Exchange, the QHP issuer needs to comply with at least the following requirements:

(1) *QHP issuer general requirements.* (i) The QHP issuer follows the enrollment process for qualified individuals consistent with § 156.265.

(ii) The QHP issuer's Web site provides applicants the ability to view QHPs offered by the issuer with the data elements listed in § 155.205(b)(1)(i) through (viii) of this subchapter.

(iii) The QHP issuer's Web site clearly distinguishes between QHPs for which the consumer is eligible and other non-QHPs that the issuer may offer, and indicate that advance payments of the premium tax credit and cost sharing reductions apply only to QHPs offered through the Exchange.

(iv) The QHP issuer informs all applicants of the availability of other QHP products offered through the Exchange through an HHS-approved universal disclaimer and displays the Web link to and describes how to access the Exchange Web site.

(v) The QHP issuer's Web site allows applicants to select and attest to an advance payment of the premium tax credit amount, if applicable, in accordance with § 155.310(d)(2) of this subchapter.

(2) [Reserved]

(b) *Direct enrollment in a Federally-facilitated Exchange.* The individual market Federally-facilitated Exchanges will permit issuers of QHPs in each Federally-facilitated Exchange to directly enroll applicants in a manner that is considered to be through the Exchange, pursuant to paragraph (a) of this section, to the extent permitted by applicable State law.

(1) The QHP issuer must comply with applicable requirements in § 155.221 of this subchapter.

(2) The QHP issuer must provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, or sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).

[78 FR 54143, Aug. 30, 2013, as amended at 81 FR 94182, Dec. 22, 2016; 83 FR 17070, Apr. 17, 2018; 84 FR 17568, Apr. 25, 2019; 85 FR 37248, June 19, 2020; 89 FR 37703, May 6, 2024]

§ 156.1240 Enrollment process for qualified individuals.

(a) *Premium payment.* A QHP issuer must—

(1) Follow the premium payment process established by the Exchange in accordance with § 155.240.

(2) At a minimum, for all payments in the individual market, accept paper checks, cashier's checks, money orders, EFT, and all general-purpose pre-paid debit cards as methods of payment and present all payment method options equally for a consumer to select their preferred payment method.

(3) For payments in the individual market made using a payment method described in paragraph (a)(2) of this section, accept premium payments made by or on behalf of an enrollee in connection with an individual coverage HRA (as described in § 146.123(b) of this

subchapter) or qualified small employer health reimbursement arrangement (as described in section 9831(d)(2) of the Internal Revenue Code of 1986, as amended) in which the enrollee is enrolled.

(b) [Reserved]

[78 FR 54143, Aug. 30, 2013, as amended at 86 FR 6178, Jan. 19, 2021]

§ 156.1250 Acceptance of certain third party payments.

Issuers offering individual market QHPs, including stand-alone dental plans, and their downstream entities, must accept premium and cost-sharing payments for the QHPs from the following third-party entities from plan enrollees (in the case of a downstream entity, to the extent the entity routinely collects premiums or cost sharing):

(a) A Ryan White HIV/AIDS Program under title XXVI of the Public Health Service Act;

(b) An Indian tribe, tribal organization, or urban Indian organization; and

(c) A local, State, or Federal government program, including a grantee directed by a government program to make payments on its behalf.

[81 FR 12352, Mar. 8, 2016]

§ 156.1255 Renewal and re-enrollment notices.

A health insurance issuer that is renewing an enrollment group's coverage in an individual market QHP offered through the Exchange (including a renewal with modifications) in accordance with §147.106 of this subchapter, or that is nonrenewing coverage offered through the Exchange and automatically enrolling an enrollee in a QHP under a different product offered by the same QHP issuer through the Exchange in accordance with §155.335 of this subchapter, must include the following information in the applicable notice described in §147.106(b)(5), (c)(1), or (f)(1) of this subchapter:

(a) Premium and advance payment of the premium tax credit information sufficient to notify the enrollment group of its expected monthly premium payment under the renewed coverage, in a form and manner specified by the Exchange, provided that if the Exchange does not provide this information to enrollees and does not require issuers to provide this information to enrollees, consistent with this section, such information must be provided in a form and manner specified by HHS;

(b) An explanation of the requirement to report changes to the Exchange, as specified in §155.335(e) of this subchapter, the timeframe and channels through which changes can be reported, and the implications of not reporting changes;

(c) For an enrollment group that includes an enrollee on whose behalf advance payments of the premium tax credit are being provided, an explanation of the reconciliation process for advance payments of the premium tax credit established in accordance with 26 CFR 1.36B–4; and

(d) For an enrollment group that includes an enrollee being provided cost-sharing reductions, but for whom no QHP under the product remains available for renewal at the silver level, an explanation that in accordance with §155.305(g)(1)(ii) of this subchapter, cost-sharing reductions are only available to an individual who is not an Indian if he or she is enrolled in a silver-level QHP.

[79 FR 53006, Sept. 5, 2014]

§ 156.1256 Other notices.

As directed by a Federally-facilitated Exchange, a health insurance issuer that is offering QHP coverage through a Federally-facilitated Exchange or a State-based Exchange on the Federal platform must notify its enrollees of material plan or benefit display errors and the enrollees' eligibility for a special enrollment period, included in §155.420(d)(12) of this subchapter, within 30 calendar days after being notified by a Federally-facilitated Exchange that the error has been fixed, if directed to do so by a Federally-facilitated Exchange.

[81 FR 94183, Dec. 22, 2016]

PART 157—EMPLOYER INTERACTIONS WITH EXCHANGES AND SHOP PARTICIPATION

Subpart A—General Provisions

Subpart B [Reserved]

Subpart C—Standards for Qualified Employers

AUTHORITY: Title I of the Affordable Care Act, Sections 1311, 1312, 1321, 1411, 1412, Pub. L. 111–148, 124 Stat. 199.

SOURCE: 77 FR 18474, Mar. 27, 2012, unless otherwise noted.

Subpart A—General Provisions

§ 157.10 Basis and scope.

(a) *Basis.* This part is based on the following sections of title I of the Affordable Care:

(1) 1311. Affordable choices of health benefits plans.

(2) 1312. Consumer Choice.

(3) 1321. State flexibility in operation and enforcement of Exchanges and related requirements.

(4) 1411. Procedures for determining eligibility for Exchange participation, advance payments of the premium tax credit and cost-sharing reductions, and individual responsibility exemptions.

(5) 1412. Advance determination and payment of the premium tax credit and cost-sharing reductions.

(b) *Scope.* This part establishes the requirements for employers in connection with the operation of Exchanges.

§ 157.20 Definitions.

The following definitions apply to this part, unless otherwise indicated:

Federally-facilitated SHOP has the meaning given to the term in § 155.20 of this subchapter.

Full-time employee has the meaning given to the term in § 155.20 of this subchapter.

Large employer has the meaning given to the term in § 155.20 of this subchapter.

Qualified employee has the meaning given to the term in § 155.20 of this subchapter.

Qualified employer has the meaning given to the term in § 155.20 of this subchapter.

Small employer has the meaning given to the term in § 155.20 of this subchapter.

[77 FR 18474, Mar. 27, 2012, as amended at 78 FR 15539, Mar. 11, 2013]

Subpart B [Reserved]

Subpart C—Standards for Qualified Employers

§ 157.200 Eligibility of qualified employers to participate in a SHOP.

(a) *General requirement.* Only a qualified employer may participate in the SHOP in accordance with § 155.710 of this subchapter.

(b) *Continuing participation for growing small employers.* A qualified employer may continue to participate in the SHOP if it ceases to be a small employer in accordance with § 155.710 of this subchapter.

(c) *Participation in multiple SHOPs.* A qualified employer may participate in multiple SHOPs in accordance with § 155.710 of this subchapter.

§ 157.205 Qualified employer participation process in a SHOP for plan years beginning prior to January 1, 2018.

(a) *General requirements.* When joining the SHOP, a qualified employer must comply with the requirements, processes, and timelines set forth by this part and must remain in compliance for the duration of the employer's participation in the SHOP.

(b) *Selecting QHPs.* During an election period, a qualified employer may make coverage in a QHP available through the SHOP in accordance with the processes developed by the SHOP in accordance with § 155.705 of this subchapter.